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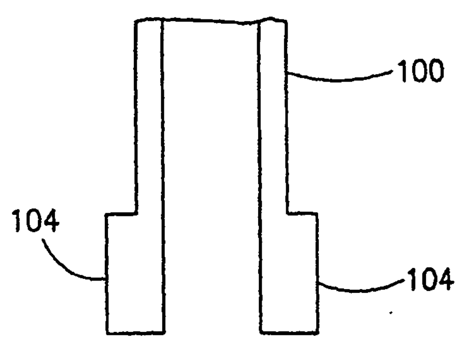


(57) Abstract: A method of preparing a graft for an anastomosis, comprising: providing a graft having a lip near an opening therein; and compressing said lip of said graft to form at least one thickened portion adjacent said opening.

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# ANASTOMOTIC DEVICES AND METHODS

## RELATED APPLICATIONS

The present application is related to the following PCT applications filed by applicants Bypass Inc., et al., PCT/IL99/00285, PCT/IL99/00284, PCT/IL99/00674, PCT/IL99/00670, PCT/IB00/00302 and PCT/IB00/00310, and an application filed on even date as the instant application, in the Israel Receiving Office of the PCT, titled "VESSEL LIP ATTACHMENT", attorney docket 088/01642, all of which designate the US, the disclosures of which are incorporated herein by reference.

## FIELD OF THE INVENTION

The present invention relates to the field of attaching two blood conduits to each other.

## BACKGROUND OF THE INVENTION

The need to connect two blood vessels or a blood vessel and a graft is well known. It is often desirable to perform an intima-to intima connection between the two vessels. However, this may require eversion of one of the blood vessels. Eversion is generally considered a difficult and demand task.

A sub-task of eversion for some types of anastomotic devices is proper penetration of the everted vessel by sharp spikes of the anastomotic connector.

## SUMMARY OF THE INVENTION

An aspect of some embodiments of the invention relates to treating the vessel tissue of at least one of the vessel of an anastomotic connection, as a non-passive tissue. Thus, various properties of the tissue are taken into account and/or utilized as part of anastomotic connection, including, for example, elasticity, plasticity and/or compressibility.

An aspect of some embodiments of the invention relates to distorting a graft or blood vessel (hereinafter the term graft is used for either or both), to simulate eversion and/or shaping of the graft tip. In an exemplary embodiment of the invention, the end of the graft is thickened to allow spikes of anastomotic device to transfix the graft parallel to its axis. These spikes may also maintain the thickening of the graft. Alternatively or additionally, the tip is stretched, to thin its wall. Alternatively or additionally, the end of the graft is compressed so that an intima portion of the graft is presented to the front or outside of the compressed graft. Alternatively or additionally, the graft is distorted so that it supports a non-perpendicular anastomosis, by an elastic desire of the graft to return to a less-distorted shape. Possibly, the angle of the connection and/or tendency to kink is modified by appropriate shaping of the graft.

In an exemplary embodiment of the invention, the compression and/or other distortion of the graft is performed by the anastomotic connector. Alternatively or additionally, the distortion is performed by a separate tool. Alternatively or additionally, the distortion is performed by a delivery system.

The anastomotic connections may be, for example, side to side, side to end or end to end. In an exemplary embodiment of the invention, an aorta is axially compressed about a holed formed therein, to assist in everting the lips of the hole and/or distorting the lips of the hole. Alternatively or additionally, to distorting the lips for an anastomotic connection, such distortion may be applied to lips of a hole in a blood vessel, for example to effect a better seal.

An aspect of some embodiments of the invention relates to controlling a shape of an anastomosis connection using an anastomosis device and/or a graft that take part in the connection. In an exemplary embodiment of the invention, the connection is made at a perpendicular angle and then the connection is modified, for example self-modified, to a new, oblique orientation.

In an exemplary embodiment of the invention, the anastomosis connector accepts bending after being deployed. Possibly, even relatively small forces suffice to bend the connector, for example, forces applied by the graft or by an external tool.

An aspect of some embodiments of the invention relates to reducing a profile (e.g., projection from a surface of a blood vessel) of an anastomosis connector after it is attached. In an exemplary embodiment of the invention, the profile is reduced by one or more of cutting, bending, twisting and/or bucking of parts of the connector. It is expected that, at least in some cases, the reduced profile will reduce the incidence of kinking of the graft. Alternatively or additionally, the pre-stressing of the graft will assist in reducing kinking.

An aspect of some embodiments of the invention relates to a vessel punch having mounted thereon an anastomotic connector. In an exemplary embodiment of the invention, the act of punching inserts the connector into the vessel, so that once it is released from the punch, the anastomosis can be completed. In an exemplary embodiment of the invention, the connector is released by rotating the punch relative to the connector.

An aspect of some embodiments of the invention relates to methods of manipulation of a graft to achieve a desired eversion, which eversion is penetrated by spikes of a connector. In an exemplary embodiment of the invention, the manipulation consists of eversion. Alternatively or additionally, the manipulation consists of converting a straight eversion into an oblique eversion, so as to pre-stress the connector so that a completed anastomosis will be oblique. Alternatively or additionally, the manipulation consists of method of advancing the

spikes to transfix the graft. It should be noted that in some embodiments of the invention, the spikes on the connector are not perpendicular to the graft at the penetration point.

In an exemplary embodiment of the invention, the spikes are assisted in penetrating the graft by suddenly releasing the spikes form a constraint, inside the everted part of the graft. Sudden release can be, for example, by releasing a lasso that holds the spikes radially compressed, by retracting an outer tube that confines the spikes or by rotating a slotted tube mounted over the connector, so that the spikes are released into the slots, simultaneously or in sequence.

In another exemplary embodiment of the invention, the spikes penetrate the graft with the help of a cap, mounted on the graft. For example, the cap can be condom-like, including a portion that extends into the lumen of the graft and a flexible membrane that can be inverted over the graft, everting the end of the graft with it. Alternatively, the cap can be a rigid cap. Twisting the cap on an everted graft will cause the spike tips to penetrate the graft, if they have not yet penetrated. Alternatively or additionally, the cap has uneven sides, for example including barbs, to unevenly pull-down the two sides. The spikes may be restrained by a lasso or over tube, during the pulling down of the cap.

In another example embodiment of the invention, the graft is mounted on a mold, which support uneven eversion, for example, using tweezers. In an exemplary embodiment of the invention, the mold comprises a cylinder with two axially extending and adjacent fingers. One spike of the connector rest between the fingers. During eversion, the tip of the vessel is brought over the finger and onto the spike. Alternatively to using tweezers and a special mold, an external tool is used, for example a pad having an inwards pointing barb. The pad slides along a tube enclosing the graft and the barb selectively engages only that part of the graft that is to be pulled down, thus stretching only that part.

In other embodiments of the invention, a manual probe is used to ensure that all the spikes penetrate the graft. In an exemplary embodiment of the invention, the probe is a Y shaped probe with a wire between the two prongs of the Y. This wire can be used to urge the graft, adjacent the spike tip, onto the spike. Alternatively or additionally, this wire is used to push back the spike, so that it can be suddenly released to penetrate the graft.

An aspect of some embodiments of the invention relates to an angular eversion tool that includes markings thereon to allow a person everting the graft to achieve a desired oblique angle in an anastomosis by using a graft everted using the marked tool.

An aspect of some embodiments of the invention relates to a split delivery system, in which the delivery system is split after the anastomosis is completed, to remove the system

from the graft. In an exemplary embodiment of the invention, a line on which the system is split is not straight. In particular, the split line meanders so that, at a point where the graft is inserted into the delivery system, the split line will not lie along a line between the graft and the system tip. Thus, the vessel is less likely to catch on the split line.

An aspect of some embodiments of the invention relates to a two part anastomotic connector in which the connector defines a ring around the outside of the anastomosis location. In an exemplary embodiment of the invention, this ring is used to guide a desirable distortion of a vessel tip of at least one of the attached vessels. In an exemplary embodiment of the invention, the ring is defined by a part of the device mounted on a side vessel of an end-to-side connection. A potential advantage of the two part device is that the locking mechanism is thin, so the profile of the device can be low. Another potential advantage is that the distortion of the vessel forms a thickening and/or eversion, so that a better seal may be achieved.

There is also provided in accordance with an exemplary embodiment of the invention, a method of preparing a graft for an anastomosis, comprising:

providing a graft having a lip at an opening therein; and

compressing said lip of said graft to form at least one thickened portion adjacent said opening. Optionally, said thickening is uniform around said opening. Alternatively, said thickening is non-uniform around said opening. Optionally, said thickening is non-uniform in length. Alternatively or additionally, said thickening is non-uniform in thickness.

In an exemplary embodiment of the invention, said thickening is selected to achieve a desired pre-stressing of said graft for an oblique anastomotic connection. Alternatively or additionally, said thickening is selected to achieve a match between the lips of two vessels. Alternatively or additionally, said thickening is selected to achieve a size match between the lip of the graft and the lip of an opening in a target vessel. Alternatively or additionally, said thickening is selected to achieve a minimum size of seal area between the lip of the graft and the lip of an opening in a target vessel.

In an exemplary embodiment of the invention, the method comprises transfixing said thickening with at least one spike.

In an exemplary embodiment of the invention, said spike is axially disposed with respect to said graft. Alternatively, said spike is obliquely disposed with respect to said graft.

In an exemplary embodiment of the invention, said thickening is maintained in shape by a connector.

In an exemplary embodiment of the invention, compressing said lip comprises compressing using an anastomotic connector. Alternatively or additionally, compressing said lip comprises compressing using a graft compression tool.

In an exemplary embodiment of the invention, compressing said lip comprises everting an intima of said graft at least 90°. Alternatively or additionally, compressing said lip comprises everting an intima of said graft at least 120°. Alternatively or additionally, compressing said lip comprises everting an intima of said graft at least 160°.

In an exemplary embodiment of the invention, said everting matches said intima to an intima of a target vessel.

In an exemplary embodiment of the invention, said opening is an opening in side of said graft. Alternatively, said opening is an opening in an end of said graft.

In an exemplary embodiment of the invention, said graft is a blood vessel. Optionally, said graft is a mammary artery.

In an exemplary embodiment of the invention, said graft is a synthetic graft.

In an exemplary embodiment of the invention, the method comprises attaching said graft to a blood vessel. Alternatively or additionally, the method comprises attaching said graft to a synthetic graft.

There is also provided in accordance with an exemplary embodiment of the invention, a connector adapter to be distorted for oblique connections, comprising:

a plurality of interconnected segments, at least some of said segments including a forward spike or a backward spike; and

a plurality of distortable portions defined between said segments, wherein said portions are adapted to support a distortion from a straight anastomosis to an oblique anastomosis. Optionally, said distortable portions comprise at least one ring. Alternatively or additionally, are designated in a ring that interconnects said segments.

In an exemplary embodiment of the invention, said distortable portions are annealed.

In an exemplary embodiment of the invention, said spikes are self extending. Alternatively, said distortable portions are plastically deformable.

In an exemplary embodiment of the invention, said distortable portions are pre-stressed to mach an oblique connection configuration. Alternatively or additionally, said distortable portions are unevenly distributed on said connector. Optionally, said distribution matches an expected amount of distortion at the different parts of said connector.

There is also provided in accordance with an exemplary embodiment of the invention, a method of creating an oblique eversion in a graft, comprising:

everting a graft to have a straight everted sleeve; and

differentially extending one side of the sleeve, to form an oblique eversion. Optionally, said everting comprises everting over a connector having spikes. Optionally, said spikes are fully extended during said everting. Optionally, said method comprises assisting said spikes to penetrate said sleeve after said differentially extending.

In an exemplary embodiment of the invention, said spikes are partially extended during said everting. Optionally, the method comprises fully extending said spikes to penetrate said sleeve.

In an exemplary embodiment of the invention, said spikes are not extended during said everting. Alternatively or additionally, differentially extending comprises extending only part of said sleeve. Alternatively, differentially extending comprises extending all of said sleeve. Alternatively, differentially extending comprises manually pulling down said side using tweezers.

In an exemplary embodiment of the invention, differentially extending comprises pulling down said side using a pad that slides along said graft, which pad includes a vessel engaging element to engage said side. Alternatively, differentially extending comprises pulling down said side using a tube that slides along said graft, which tube includes a vessel engaging element to engage said side. Optionally, said tube comprises at least a second vessel engaging element, to engage an opposite side of said sleeve. Alternatively or additionally, said tube is capped, to prevent over sliding of said tube over said graft.

There is also provided in accordance with an exemplary embodiment of the invention, a method of creating an oblique eversion in a graft, comprising:

mounting said graft inside a graft holder having a slotted axial extension;

mounting a connector on said graft such that a spike of said connector exits through said slot; and

everting said graft on said tube, such that a portion everted over said extension is longer than a portion everted not over said extension.

There is also provided in accordance with an exemplary embodiment of the invention, a method of penetrating non-perpendicular pointing spikes of a connector into an everted graft, comprising:

radially compressing said spikes;

everting said graft over said connector; and

suddenly releasing said spikes, to penetrate said graft. Optionally, said radially compressing aligns said spikes to be more perpendicular to said graft. Alternatively, radially

compressing comprises restraining said spikes using a slotted tube and wherein suddenly releasing comprises rotating said tube so that said spikes align with and pass through said slots. Optionally, all of said spikes are aligned simultaneously with said slots by said rotation. Alternatively, not all of said spikes are aligned simultaneously with said slots by said rotation.

In an exemplary embodiment of the invention, radially compressing comprises restraining said spikes using an over-tube and wherein suddenly releasing comprises retracting said tube relative to said spikes so that said spikes are released. Optionally, said over-tube comprises a graft holder for said graft. Alternatively, said over-tube is separate from a graft holder for said graft.

In an exemplary embodiment of the invention, retracting said tube relative to said spikes comprises advancing said connector.

In an exemplary embodiment of the invention, retracting said tube relative to said spikes comprises retracting said over-tube.

In an exemplary embodiment of the invention, said spikes are partially extended so they can contact said graft, prior to said suddenly releasing.

In an exemplary embodiment of the invention, said spikes are not all the same length, so that when released they do not all penetrate said graft at a same time.

In an exemplary embodiment of the invention, said tube is oblique.

In an exemplary embodiment of the invention, radially compressing comprises restraining said spikes using a looped thread. Optionally, said looped thread comprises a slipknot.

There is also provided in accordance with an exemplary embodiment of the invention, a method of penetrating non-perpendicular pointing spikes of a connector into an everted graft, comprising:

everting said graft over said connector;

placing a cap on said everted graft; and

manipulating said cap to cause penetration of said spikes into said graft. Optionally, manipulating comprises rotating said cap. Alternatively or additionally, manipulating comprises axially displacing said cap.

There is also provided in accordance with an exemplary embodiment of the invention, a method of everting a graft, comprising:

mounting said graft in a graft holding tube;

providing a conical membrane inside a lumen of said graft; and

everting said membrane to effect an eversion of said graft. Optionally, said conical membrane comprises a relatively rigid base ring. Alternatively or additionally, said conical membrane comprises a relatively rigid extension from its tip.

In an exemplary embodiment of the invention, said everting comprises obliquely everting said conical membrane.

There is also provided in accordance with an exemplary embodiment of the invention, a split graft holder, comprising:

a tube having a tip for the exit of a graft, defining:

a side opening for receiving the graft through a lumen of said tube to said tip; and

a split line along said tube axis and meeting said side opening, for splitting said holder to remove said holder from a graft, after said graft is attached to another blood conduit,

wherein

said split line does not axially meet said side opening, at a side of said opening near said tip of said tube. Optionally, said split line meets said opening from its side.

There is also provided in accordance with an exemplary embodiment of the invention, a reducing profile anastomotic connector, comprising:

a ring section;

a spikes section comprises a plurality of spikes, wherein said spikes section defines a collapsing portion, for axial collapsing of said spikes section. Optionally, said collapsing portion buckles. Alternatively or additionally, said collapsing portion twists. Alternatively or additionally, said collapsing portion folds out.

In an exemplary embodiment of the invention, said collapsing portion self-deforms. Alternatively, said collapsing portion plastically deforms.

There is also provided in accordance with an exemplary embodiment of the invention, a combined hole punching and graft delivery device, comprising:

a body, having therein at least one recess for receiving a spike of a connector; and

a sharp tip retractable relative to said body, wherein said sharp tip and said body define between them a blood vessel wall receiving area. Optionally, said recess includes a protrusion, for selectively releasing said spike when said body is rotated relative to said spike. Alternatively or additionally, said spike is pre-stressed to self extend out of said recess. Alternatively, said spike radially extends out of said recess when it is retracted.

There is also provided in accordance with an exemplary embodiment of the invention, a graft everting tool, comprising:

a base ring;

an extension adapted to be inserted in a graft; and

a conical membrane-like element connecting said base and said extension, and adapted to engage an inside of a blood vessel,

wherein said membrane is flexible enough to be everted. Optionally, said tool is adapted to evert obliquely. Alternatively or additionally, said tool has a non-uniform graft property, so as to effect an oblique eversion when it is used to evert a graft.

There is also provided in accordance with an exemplary embodiment of the invention, a tool for compressing a tip of a graft, comprising:

an outer mandrel mounted over the graft and reaching to about an opening in the graft;

an inner mandrel mounted inside the graft and reaching to about said opening; and

a base,

wherein said base and said two mandrel define a space for said graft to extend into when the mandrels are brought together. Optionally, said inner mandrel is mounted on said base. Alternatively or additionally, said inner mandrel is expandable. Alternatively or additionally, said inner mandrel is adapted to engage at least a portion of said graft. Alternatively or additionally, said outer mandrel is adapted to engage at least a portion of said graft.

There is also provided in accordance with an exemplary embodiment of the invention, a tool for forming an oblique eversion from a graft everted over a graft holder, comprising:

a body shaped to slide over said everted graft; and

at least one graft engaging element for selectively engaging only one side of said everted graft. Optionally, said body comprises a tube. Alternatively, said body comprises a tube segment.

In an exemplary embodiment of the invention, said body is capped to prevent axial motion beyond a certain amount.

In an exemplary embodiment of the invention, the tool comprises at least a second graft engaging element for engaging a second side of said everted graft.

There is also provided in accordance with an exemplary embodiment of the invention, a tool for forming an oblique eversion for a graft, comprising:

a tube; and

at least one axial extension of said tube, such that a spiked connector disposed in said tube can project at least one of its spikes near a base of said projection. Optionally, said at least

one projection comprises at least two projections defining a slot between them, with said spike extending through said slot.

There is also provided in accordance with an exemplary embodiment of the invention, a tool for forming an oblique eversion for a graft, comprising:

a tube adapted for having a graft and a connector mounted therein; and

an over-tube which radially restrains at least one spike of said connector, wherein said connector can be moved relative to said over-tube. Optionally, said over tube is slotted and wherein said motion is rotation. Alternatively or additionally, said motion comprises axial motion of said connector relative to said over-tube. Alternatively or additionally, said tube is a same element as said over tube.

In an exemplary embodiment of the invention, said over-tube is oblique.

There is also provided in accordance with an exemplary embodiment of the invention, a tool for assisting spike penetration into an everted graft; comprising:

a graft and connector holder having a graft everted thereon; and

a cap having an inner diameter larger than an outer diameter of said graft and connector holder, for mounting on said everting graft.

There is also provided in accordance with an exemplary embodiment of the invention, a tool for assisting spike penetration into an everted graft; comprising:

a handle, defining at least two arms; and

a wire between said two arms,

wherein said tool is adapted for assisting penetration of a spike into an everted graft.

## BRIEF DESCRIPTION OF THE FIGURES

Non-limiting embodiments of the invention will be described with reference to the following description of exemplary embodiments, in conjunction with the figures. The figures are generally not shown to scale and any measurements are only meant to be exemplary and not necessarily limiting. In the figures, identical structures, elements or parts which appear in more than one figure are preferably labeled with a same or similar number in all the figures in which they appear, in which:

Figs. 1A-1D show an everted graft and grafts with simulated eversion, in accordance with exemplary embodiments of the invention;

Figs. 2A-2C illustrate various anastomotic connections using thickened grafts, in accordance with exemplary embodiments of the invention;

Figs. 2D and 2E illustrate the use of graft distortion to vary the graft layout, in accordance with an exemplary embodiment of the invention;

Fig. 3 illustrates a blood vessel distorter, in accordance with an exemplary embodiment of the invention;

Figs. 4A and 4B illustrate a distortable connector, in straight and distorted configurations, in accordance with an exemplary embodiment of the invention;

Figs. 4C and 4D are side cross-sectional views of an anastomotic connection utilizing the connector of figs. 4A and 4B, before and after relaxation of strain;

Figs. 5A-5E illustrate a two part connector and a method of deploying such a connector, in accordance with an exemplary embodiment of the invention;

Figs. 6A-6E illustrate methods and apparatus for reducing an axial profile of an anastomotic device, in accordance with exemplary embodiments of the invention;

Figs. 7A and 7B illustrate the working of a flexible graft everter, in accordance with an exemplary embodiment of the invention;

Figs. 8A-8D illustrate a lasso-based release mechanism, in accordance with an exemplary embodiment of the invention;

Figs. 8E-8F show two different lasso configurations for use with the embodiments shown in Figs. 8A-8D;

Figs. 9A-9D illustrate a slotted-tube mechanism for sudden release of spikes of a connector;

Fig. 10A and 10B illustrate an over-tube based spike penetration method and apparatus, in accordance with an exemplary embodiment of the invention;

Figs. 11A-11C illustrate a cap based technique and apparatus for spike penetration, in accordance with an exemplary embodiment of the invention;

Figs. 12A-12C illustrate a probe and a spike penetration method using the probe, in accordance with an exemplary embodiment of the invention;

Figs. 13A and 13B illustrate a tool for oblique eversion, in accordance with an exemplary embodiment of the invention;

Figs. 14A and 14B illustrate a method of converting an even eversion into an oblique eversion, in accordance with an exemplary embodiment of the invention;

Figs. 15A-15C illustrate an alternative method of converting an even eversion into an oblique eversion, in accordance with an exemplary embodiment of the invention;

Figs. 16A and 16B illustrate a cap-like tool for converting a perpendicular eversion into an oblique eversion, in accordance with an exemplary embodiment of the invention;

Fig. 17 illustrates an exemplary combined hole punch and connector inserter tool, in accordance with an exemplary embodiment of the invention; and

Figs. 18A and 18B illustrate a graft delivery system, in accordance with an exemplary embodiment of the invention.

## DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

Some embodiments of the invention utilize the fact that the vascular tissue has non-trivial mechanical properties. In an exemplary embodiment of the invention, the ends of a graft vessel are compressed, to achieve various effects, for example, pre-stressing the graft to be inclined to a certain post-anastomotic shape, thickening the graft to support transfixing of the graft, at non-perpendicular angles, using spikes of a connector and/or presenting an intima to an anastomosis connection, without a complete eversion of the graft. It is noted that thickening the ends of the graft may also improve the leakage-prevention properties of the anastomotic connection. In some embodiments of the invention, a graft having the desired thickening and/or distortion is manufactured.

Figs. 1A-1D show an everted graft and grafts with simulated eversion, in accordance with exemplary embodiments of the invention. Fig. 1A shows a standard everted vessel 100, having everted lips 102.

Fig. 1B shows vessel 100 with its end compressed, so that a thickened portion 104 is formed at the distal end of the graft. This thickening may, for example, match a greater vessel thickness of a target vessel and/or provide for a better seal.

Fig. 1C shows vessel 100 with its end unevenly compressed, so that thickened portions 106 and 108 are of different lengths. The end-face of the vessel is perpendicular to the vessel axis. In an exemplary embodiment of the invention, this type of distortion pre-stresses the graft, so that when the anastomosis is completed, the graft will naturally curve in a desired connection, for an oblique connection or for a perpendicular connection with a curving graft. It is expected that thus pre-stressing may, in some cases, reduce a tendency to kink.

Fig. 1D shows an alternative uneven thickening, in which thickened ends 110 and 112 define an oblique end face for vessel 100. An oblique connector 114 is shown mounted on vessel 100. Connector 114 comprises, for example, a ring 116 and a set of longer spikes 118 that transfix the longer thickened portion 110 and a set of shorter spikes 120 that transfix the shorter thickened portion 112. As can be seen, the anastomotic connector may be material in maintaining the axially compressed condition of the vessel end, however, this is not required. In Figs. 1C and 1D, the graft way be originally cut with at an angle, or not.

The thickening may be, for example, a multiple of the original graft wall, for example, a factor of 1.1, 1.5. 2.0, 2.5, 3.0 or any greater, smaller or intermediate number. Alternatively or additionally, it may be absolute, for example, 0.5 mm. 1 mm. 1.5 mm or 2 mm, or any

greater, smaller or intermediate size. The length of the thickening may vary, for example, being 0.3 mm, 0.6 mm, 1 mm, 2 mm, 4 mm or any greater, smaller or intermediate size. Alternatively or additionally, the length is a function of the graft diameter, for example, being a factor of 0.3, 0.5, 1, 1.5 or any greater, smaller or intermediate number. The angle (possibly measured at a short distance from the anastomosis location) of an oblique connection may be, for example, 10°, 20°, 30°, 50°, 70°, 80° or any greater, smaller or intermediate angle. In some cases, the angle is with the flow direction, in others, perpendicular or against the flow direction.

Figs. 2A-2C illustrate various anastomotic connections using thickened grafts, in accordance with exemplary embodiments of the invention. In these figures, the graft is vessel 200 and the target vessel is either an end vessel 202 or a side vessel 204. In an exemplary embodiment of the invention, side vessel 204 is an aorta or other thick artery, which has a thick wall and may be difficult to invert. Alternatively, it may be a graft or a stent graft.

Fig. 2A shows two exemplary end-to-end anastomosis connections, 206 and 208. In anastomosis 206, the tips of the vessels are thickened, thereby possibly affording a better seal and/or compensating for any unevenness in the vessels. In anastomosis 208, the marked area indicates the intima of the vessels. As shown, one or both vessels are distorted so that their intimas meet, even though the vessels are not completely everted. Such distortion can be achieved, for example, by pulling back the outer side of the thickened portion, pulling along the intima portion. Alternatively, the vessels may be distorted so that the outside of the vessels meet, for example by stretching the outside of the vessels, rather than the intima.

Fig. 2B shows two exemplary end-to-side anastomosis connections, 210 and 212. In connection 210, the lip of side vessel 204 is partially everted. Alternatively, it may be axially compressed, to make it thicker. In connection 212, the vessel lip is not modified, and the thickening of the tip of vessel 200 may afford a better seal. The intima of vessel 200 may or may not be exposed, as shown in Fig. 2A.

Fig. 2C shows two additional exemplary end-to-side anastomosis connections, 214 and 216. In connection 214, the end of vessel 200 is thickened and distorted to have a non-uniform face, so that an extension of vessel 200 enters side vessel 204. Possibly, some or all of the extension exposes an intima, as shown in the Fig. Optionally, as shown, a thickening of vessel 200 remains outside vessel 204 and in contact with its outer surface, for example for providing a better seal and/or a more stable seal. In connection 216, the lip of side vessel 204 is partially everted, to contact its intima with vessel 200.

As shown in Fig. 2C, the front face of vessel 200 need not be planar, and can vary. In addition, the side profile of the thickened part can vary, for example to include a bump that abuts against the walls of the opening in the side vessel, possibly providing a sealing ring.

Alternatively, similar distortions may be used for side-to side connections, or for hole closures (both lips from same blood vessel). In such connections, intima-to-intima meeting may be desirable, alternatively or additionally to matching up of vessel lips over a large area. In an exemplary embodiment of the invention, an anastomosis connector is converted into a hole closure device by providing a membrane (e.g., part of a graft) across the lumen of the connector.

The various contact configurations and vessel distortions shown in Figs. 2A-2C may be maintained using a variety of methods, for example, sutures, tissue adhesive, connectors that transfix the distorted portion with a spike and/or connectors that apply a constraining force on the distorted portion.

It should be noted that distortion of a vessel may be easier to achieve than eversion, for example if the vessel is fragile or calcified or if the tip of the vessel is in a hard to reach area.

Figs. 2D and 2E illustrate the use of graft distortion to vary the graft layout, in accordance with an exemplary embodiment of the invention. In Fig. 2D, a graft is bent by thickening only one side of the graft (or differentially thickening two sides) to form a thickening 222 are a bending location thereof. The thickening may be maintained, for example, by a pin or staple 224. In Fig. 2E, a graft is shortened, by forming thickenings 228 at its center, optionally holding them together using a pin 230. In some cases, the selective distortion of grafts is practiced after the anastomosis is completed, to assure that the graft will not kink or otherwise lay in an undesirable configuration.

The distorted grafts and/or vessels may be of any type, for example synthetic, xenologous, autologus (e.g., veins and arteries), and cadaver tissue. However, the LIMA and RIMA mammary arteries appear to have significant potential for distortion. Other exemplary suitable target vessels include the radial and gastro-epiploic arteries. It should be noted that the methods described herein can be applied to a vessel that is connected at one or both ends to the body, or to a vessel that is not connected to the body. The vessel may be inside the body, for example being connected or being provided through a tube, for example endocscopically or transvascularly. Alternatively, at least a part of the vessel that is worked on outside the body.

Fig. 3 illustrates an exemplary blood vessel distorter 300, in accordance with an exemplary embodiment of the invention. A vessel 302 is mounted on an inner tubular support

304. An outer tube 306 engages vessel 302 at least at an engagement portion 308. At the base of tube 312 there is defined a moat 315 by a surrounding wall 312 and a base element 313.

When tube 306 is advanced, it pushes vessel 302 into the moat, where unduly radial expansion is prevented by wall 312. If tube 306 is slightly shy from the vessel edges, as shown, the vessel end will distort to the form shown as a dotted line by reference 314. In an exemplary embodiment of the invention, tube 306 engages vessel 302 by providing an over tube 310 that radially compress tube 306, or at least engaging portion 308 thereof.

In an alternatively embodiment of the invention, vessel 302 is held by tube 304, for example by forcing a widening wedge 316 into a lumen of tube 304.

The outer surface of tube 304 and the inner surface of tube 306 may be smooth or it may be rough, at least at some locations. By suitable selection of rough locations and the tube that engages vessel 302, various effects can be achieved. In one example, engaging vessel 302 via its inner surface, prevents motion of the intima. In another example, after the vessel is compressed, tube 304 is expanded to hold the intima and tube 306 is slightly retracted, causing the intima to be exposed at the front or outside of vessel 302.

A connector may be mounted on the compressed vessel in various manners. In one example, the connector sits inside moat 315. In another example, the connector is between tubes 304 and 306. Possibly, portion 308 is axially slotted, to receive spikes of the connector. Alternatively or additionally, the connector is mounted in a recess in portion 308. Alternatively or additionally, base 313 and/or tube 306 are slotted, to accommodate the connector. It should be noted that tubes 304 and 306 can have a non-circular cross-section, for example, elliptical or polygonal cross-sections. In some embodiments of the invention, the distortion includes twisting of vessel 302. In some embodiments, this twisting will be assisted by a spiral pattern on tube 304 and/or tube 306. Further, base 313 may not be flat, for example to assist in achieving the distortions shown in Fig. 2C.

The distorted blood vessel may be distorted plastically, elastically or a combination of elastic and plastic distortion. The vessel may be cooled, to prevent it from returning to the undistorted configuration

When compressing the lips of a side opening, the inner tube may have the form of a T-shaped mandrel, for example, and the outer tube may be slotted, to receive the graft.

Referring back to Fig. 1C, when the graft is released, for example after an anastomosis is completed, the graft will tend to assume a non-perpendicular orientation to a side vessel to which it is attached. This is also the case where a graft is everted in a non-even manner. The

strain caused by the uneven eversion or the uneven compression will tend to curve the graft. Such curvature may be desirable in an anastomotic connection.

If the anastomotic connector has a low enough profile (e.g., protrusion from the inner surface of the target vessel), the curving of the graft can proceed without the connector itself affecting the curve. Alternatively, the connector itself may be oblique.

In an alternative embodiment of the invention, a connector that is naturally distortable into an oblique configuration, is provided. Such a connector supports an oblique connection. Possibly, the connector may be pre-stressed into a distorted configuration. Alternatively or additionally, the connector may be distorted by strain release in the graft. Alternatively or additionally, the connector may be manually distorted after the anastomosis is completed.

Figs. 4A and 4B illustrate a side of a distortable connector 400, in straight and in distorted configurations, in accordance with an exemplary embodiment of the invention. Connector 400 comprises a plurality of forward spikes 404 and a plurality of backward spikes 402. The sets of spikes are interconnected using a ring 408 that includes distortable sections 406. In an exemplary embodiment of the invention, sections 406 are designed to act as hinges. Alternatively or additionally, sections 406 distort in a manner which allows them to return to a pre-stressed shape, for example by being elastic, super-elastic or shape-memory pre-stressed. Alternatively, sections 406 are plastically deformable. The distribution of sections 406 may be uniform or non-uniform, for example being greater at ring areas where a greater distortion is required (as shown). This general design (providing distortion sections) may be applied to other anastomotic connectors, for example, to annular ring connectors (on the ring itself) two-part connectors (on one or both parts) or to connectors with multiple axial rings or cell elements (at spaced apart radial locations).

Connector 400 may be pre-stressed to the configuration shown in Fig. 4B, however, it is deployed as shown in Fig. 4A, for example using an axial restraining element (e.g., a slotted over-tube), that limits the axial position of the ring 408.

In an exemplary embodiment of the invention, pairs of distortable sections 406 are provided on axially pointing sections of ring 408, so that axial distortion can be achieved by non-axial motion of the axial sections between distortable sections 406.

Figs. 4C and 4D are side cross-sectional views of an anastomotic connection utilizing connector 400, before and after relaxation of strain. In Fig. 4C, the anastomosis is just completed, for example, using a perpendicular hole-punch and a perpendicular delivery system. A tube 410 may be provided to maintain this perpendicular orientation. Tube 410 may be a same tube that is used as a graft holder for providing the vessel and the connector to the

anastomosis connection. When tube 410 is removed (e.g., for self-deforming or graft based-deforming embodiments), or if holder 410 is rotated on its end (e.g., for plastic embodiments) the connection distorts and assumes the oblique configuration shown in Fig. 4D. The shape of the lumen may remain circular or it may also distort, for example into an ellipse.

In some embodiments of the invention, the distortion of connector 400 also involves radial expansion, for example, in a self-deforming connector, thereby sealing the anastomotic connection. Alternatively, the device may elastically expand radially, while being plastically distorted, for example by selective annealing of sections 406, for example using a contact heater, or an energy beam.

In some embodiments of the invention, the connector itself may perform the eversion and/or other distortion of the graft.

Figs. 5A-5E illustrate a two part connector and a method of deploying such a connector, in accordance with an exemplary embodiment of the invention. Fig. 5A shows a configuration 500 including two parts, an end configuration 502 and a side configuration 504.

End configuration 502 includes a graft 506 having a first connector part 508 mounted thereon. As shown, connector 508 includes a plurality of spikes 510 that penetrate graft 506. The spikes may be interconnected by a ring 514 and include a locking mechanism 512. Optionally, an intra-wall spike 509 is provided to guide the distortion of the tip of graft 506. Connector 508 is held by an outer holder 516 and optionally abuts against a pusher 518.

Side configuration 504 comprises a side vessel 530 having mounted thereon a second connector part 520. Connector part 520 comprises a plurality of spikes 522 that pierce vessel 530, optionally attached to a ring 524. A locking mechanism 526 may be provided, which optionally mates with locking mechanism 512 of part 508. An outer holder 528 is provided outside of part 520. In some embodiments of the invention, holders 528 and 516 provide radially rigidity to the connector during the deployment process and may possibly replace the use of ring like elements (514, 524) in one or both connector parts.

In Fig. 5B, configuration 502 is being inserted into configuration 504. Possibly, holder 506 snugly fits into holder 528. Optionally, the two holders are slotted, to enforce certain relative rotational positions of the connectors, for example for oblique connections. Possibly, holder 528 and/or holder 516 include an inner thread, to support twisting of holder 516, while it is advanced.

In Fig. 5C, holder 516 is locked into position relative to holder 528. Attention should be taken of a volume 532 defined between connector parts 508 and 520. It should be noted that graft 506 and graft 530 are prevented from expansion into the anastomosis lumen, by spikes

522 and 510. However, expansion towards holder 528 is possible, due to a difference in radiuses between the two connector parts. In some embodiments, eversion is achieved instead of distortion.

In Fig. 5D, pusher 518 is advanced, possibly in a spiral motion, first compressing the very end of graft 506 and then completing the anastomosis by the interlocking of locking elements 512 and 526. In an exemplary embodiment of the invention, the locking elements comprises a tab punched out of a metal sheet in one element and a matching slot for the tab in the other element.

In Fig. 5E, the holders are removed, leaving a completed anastomosis connection. In an exemplary embodiment of the invention, the parts of the connector that remain in the blood flow are thin wires, for example metal or plastic.

In an exemplary embodiment of the invention, side configuration 504 is inserted with spikes 522 in a straight configuration. The spikes may be pre-stressed to be bent, and prevented from bending by bars that are later retracted. Alternatively, spikes 522 are plastically bent, for example using an anvil provide through the hole in vessel 530 (not shown). Punching out of the hole may, in some embodiments of the invention, be performed after the spikes are inserted.

Although the connectors of Figs. 5A-5E are shown for an end-to-side connection, it should be appreciated that a similar device may be used for an end-to-end connection and/or a end-to-side connection. In such connections, as well as a side-to-end connection, the lips of one or both vessel may be distorted.

Figs. 6A-6E illustrate methods of reducing an axial profile of an anastomotic device, in accordance with exemplary embodiments of the invention. These illustrations are shown on a simple two part anastomotic device. However, they may be applied to other two part devices or to one part devices that include ring and spike portions, for example as shown in the above referenced PCT applications.

Fig. 6A illustrates a two part anastomotic connector 600 comprising a ring portion 602, for mounting outside an "end" vessel and a spike portion 604 for penetrating a side vessel and/or an everted portion of the end vessel. In this and other embodiments, the ring portion and the spike portion may be integral, or may be separate parts, for example slots or openings formed in the ring portion, for the spike portion. An extension 606 of spike portion 604 may be used, for example, for holding, pushing and/or pulling spike portion 604. Once the connection is completed, extension 606 is bent outwards, as shown, to reduce the axial profile of the anastomotic connection. Such bending may also server to lock the anastomotic

connection. Such bending can be achieved, for example, by advancing an over-tube that has an inclined front edge, over the side vessel. The smallest diameter of the over-tube fits between extension 606 and the vessel. However, the larger diameter is significantly greater, causing extension 606 to be bent. Alternatively, extension 606 may be twisted in place and/or sniped off.

Figs. 6B and 6C illustrate a twist based profile reduction method. A connector 610 comprises a ring 612 and a spike portion comprising a set of spikes 613 also connected to a ring 614. An extension 618 of the spikes portion protrudes above ring 612. In Fig. 6C, extension 618 has been axially retracted to a degree sufficient for performing the anastomosis, for example by bringing a vessel engaged by the spikes into contact with a graft everted on the spikes and/or ring. Extension 618 is then twisted, thereby reducing the axial extent of extension 618 and/or locking the anastomotic connection.

Figs. 6D and 6E illustrate a bending based profile reduction method. A connector 620 comprises a ring 622 and a spike 624, of which an extension 626 protrudes above the ring 622. In Fig. 6D, after the anastomosis is completed, extension 626 is advanced, so that it buckles, reducing its axial extent. In an exemplary embodiment of the invention, ring 622 is axially rotated twisted relative to spikes 624. Such rotation is useful if the slots in ring 622, through which spikes 624 fit, have a wedge profile. The rotation, urges the spikes into the narrower part of the wedge, to be snugly engaged by the ring, so that the advancing of extension 626 does not cause the post-ring parts of spikes 624 to advance.

Although the spikes portions in the above embodiments of Fig. 6 may be plastically deformed, in an alternative embodiment of the invention, the spikes are elastic, super-elastic or shape-memory materials, which self deform when a restraint (not shown) is released.

Figs. 7A and 7B illustrate the working of a flexible graft everter 706 in accordance with an exemplary embodiment of the invention. A graft 702 is mounted inside a holding tube 704, which may also be used for providing a connector (not shown). Everter 706 is inserted into the lumen of graft 702. In an exemplary embodiment of the invention, everter 706 comprises an extension 708, that fits into graft 702, a flexible portion 710 and a relatively rigid ring portion 712. Everter 706 may have the general form of a cone or a condom, for example as shown. In an exemplary embodiment of the invention, the outer surface of everter 706 may be rough or barbed, to better engage the inner surface of graft 702. In some cases, the membrane is not continuous, for example comprising a plurality of flexible rods connecting ring 712 and extension 708, or the membranes having apertures formed therein.

In operation, as shown in Fig. 7B, ring portion 712 is advanced towards graft 702, causing membrane 710 to fold, carrying graft 702 along with it, to be everted. In some embodiments of the invention, membrane 710 is designed to effect an oblique eversion, for example, by membrane 710 having a non-radially uniform flexibility, so that it does not evert uniformly. Alternatively or additionally, different parts of membrane 710 have different friction coefficients with the grafts so that some parts pull the graft more when the membrane is everted. Alternatively or additionally, holding tube 704 is oblique.

In some embodiments of the invention, instead of everting the graft, the graft is provided with an intima on its outside or front surfaces, for example, patterned to match a particular anastomosis connection configuration. In an exemplary embodiment of the invention, the graft is manufactured to include the intima. Alternatively or additionally, a layer of intima, for example an inverted graft section or a vessel flap is glued on the graft. It is noted that an inner surface of the tip of the graft may be manufactured to not include an intima, for example to facilitate attachment to an outside surface of a blood vessel.

The graft may be everted directly onto the spikes of the anastomotic connector. However, this may not be easy to do. For example, the spikes may point sideways or even backwards, rather than forwards. Alternatively or additionally, the graft may be tough enough to resist penetration by self-expanding spikes or to bend spikes that are advanced relative to the graft.

Figs. 8-10 illustrate three sudden-release mechanisms by which the spikes can be restrained and then released suddenly, to penetrate the graft.

Figs. 8A-8D illustrate a lasso-based release mechanism, in accordance with an exemplary embodiment of the invention. In Fig. 8A, a graft 802 is inserted through a graft holder 804 having mounted thereon a connector 806 with backwards pointing spikes 808. In Fig. 8B, a lasso 810 having a loop 812 is tied on spikes 808, bending them radially inwards, so that the spikes point substantially forward. Graft 802 is then everted over the lassoed connector, for example using the method shown in Fig. 7A and 7B, or using any other method. In Fig. 8C, lasso 810 is released allowing spikes 808 to spring out and penetrate graft 802. In Fig. 8D, spikes 808 have completed their penetration, possibly with some manual assistance (for example as described below), and the mounting is completed.

Figs. 8E-8F show two different lasso configurations for use with in Figs. 8A-8D. In Fig. 8E, lasso 810 includes only a single loop 812. In Fig. 8F, the lasso includes multiple loops. Both lassoes, however, can be released by pulling on the thread. Possibly, the lassoes are formed of a surgical suture material or of a thin Dacron filament.

Figs. 9A-9D illustrate a slotted-tube mechanism 900 for sudden release of spikes of a connector.

Fig. 9A shows a graft 902 mounted in a graft holder 904, along with a connector 906 having backward bending spikes 908. A slotted over-tube 910 is provided. Optionally, over-tube 910 includes a shield 912 (described below).

In Fig. 9B, over-tube 910 is advanced, so that spikes 908 are bent back and held in a step resting place 914. In addition, shield 912 prevents spikes 908 from contacting graft 902, once it is everted. The graft may then be everted over over-tube 910.

In Fig. 9C over-tube 910 is rotated, so that spikes 908 are aligned with slots 916 formed in over-tube 910, causing the spikes to exit over-tube 910 and penetrate the everted graft 902.

Fig. 9D is a top view of over-tube 910 showing slots 916, shield 912 and step-resting place 914 for spikes 908.

Although only two spikes are shown in the figure, a real connector may include greater number of spikes, for example, 4, 6, 8 or more.

Fig. 10A and 10B illustrate an over-tube based spike penetration method, in accordance with an exemplary embodiment of the invention. Fig. 10A shows a configuration 1000, in which a graft 1002 is shown mounted on a graft holder 1004 and everted over an over-tube 1010. A connector 1006 including backward pointing spikes 1008, is separated from an everted portion of graft 1002, by over-tube 1010, which over-tube also bends back spikes 1008.

In Fig. 10B, over-tube 1010 is retracted, allowing spikes 1008 to spring out and transfix graft 1002.

Alternatively to a separate over-tube, graft holder 1004 itself may serve as an over-tube, for example, by connector 1006 being axially advanced in graft holder 1004 by a pusher or a tube on which the connector is mounted (not shown).

In an exemplary embodiment of the invention, the above methods are varied so that an oblique eversion is achieved. In a first modification, over-tube 1010 is oblique, so some spikes are released first, and can pull down the graft before other spikes are released. In a second modification, not all spikes are the same length, so that some are released first, even of over-tube 1010 is not oblique.

Figs. 11A-11C illustrate a cap based technique for spike penetration, in accordance with an exemplary embodiment of the invention.

Fig. 11A shows a graft 1102 that is everted over a graft holder 1104 and a connector 1106 having backwards pointing spikes 1108. Some of the spikes may have penetrated graft 1102. A cap 1110 is provided that has an inner radius slightly greater than the outer radius of the everted graft.

In Fig. 11B, cap 1110 is mounted on the everted portion of graft 1102. This mounting typically bends the spike tips further backwards and inwards. Axial and rotational manipulation of cap 1110 has been found to cause the spikes to penetrate the everted portion of graft 1102, as shown in Fig. 11C.

Figs. 12A-12C illustrate a probe 1200 and a spike penetration method using the probe, in accordance with an exemplary embodiment of the invention. In an exemplary embodiment of the invention, the probe is used to individually force parts of a graft 1202 between a spike 1208 and a graft holder 1204, thus causing the spike to penetrate the graft, possibly due to a perpendicular angle crated between the spike tip and the graft. Possibly, as shown, a wire probe is used. Alternatively, other probe designs may be used. Alternatively or additionally, to using the probe to directly manipulate the graft tissue, in an exemplary embodiment of the invention, the probe is used to manipulate the spikes through the graft. For example, the spikes are pushed back using the probe so that they can be suddenly released and thus penetrate the graft.

Fig. 12A illustrates a Y shaped probe 1200, comprising a handle 1216, two arms 1212 and a thread 1214 connecting the two arms. Such a probe may be similar in design to a commonly used teeth cleaning (flossing) probe.

Fig. 12B shows a graft 1202 everted over a graft holder 1204 and a connector 1206 having backwards pointing spikes 1208. Thread 1214 of probe 1200 is shown engaging a portion of the everted graft between a spike tip and graft holder 1204. In Fig. 12B, the thread is brought up, causing the spike tip to penetrate the graft. The rest of the spikes may be handled in turn.

In another exemplary embodiment of the invention, the spikes of the connector are mounted in a short hollow and sharp tipped tube. This tube maintains the spikes to be axial, so that they can more easily penetrate the vessel. Possibly, the spike tips are not sharp, for example to prevent inadvertent tissue penetration when deployed. After the connector is advanced (and the tubes penetrate the graft), the tubes are removed, for example using tweezers, so that the spike scan bend to their backwards pointing configuration.

Figs. 13A and 13B illustrate a tool 1300 for oblique eversion, in accordance with an exemplary embodiment of the invention. Tool 1300 comprises a graft holding tube 1304,

having at its end one or more finger extensions 1314. As will be shown in Fig. 13B, these finger extensions serve to assist in everting some parts of a graft 1302 more than others. Although only two fingers, for one spike 1308 (explained below) are shown, a plurality of fingers, possibly or different lengths, may be provided on tube 1304. It should be appreciated that in this and other embodiments of the invention, the graft holder may be used for delivering the graft and/or the connector to the anastomotic connection. Alternatively, a separate graft holder for delivery may be provided.

Fig. 13B shows tool 1300 in operation. A graft 1302 is everted over the end of tube 1304. Two spikes 1308 of a connector (not shown) are shown, one at a part of tube 1304 where there are no fingers, and one near a finger 1314 (as shown also in Fig. 13A). A portion 1310 of graft 1302 is everted over one spike 1308. However, when a portion 1312 of graft 1302 is everted, portion 1312 is first be brought over a finger 1314, thus providing an uneven eversion. In some embodiments of the invention, the length of finger 1314 is controllable, for example, by finger 1314 comprising a movable bar mounted on an outside of tube 1304. Alternatively or additionally, fingers 1314 are part of an inner tube (not shown) which is optionally later retracted or removed.

Figs. 14A and 14B illustrate a method of converting an even eversion into an oblique eversion, in accordance with an exemplary embodiment of the invention.

In Fig. 14A, a graft 1402 is shown everted over a graft holder 1404 and a pair of spikes 1408 of a connector (not shown). A portion 1412 of graft 1402 is to be everted more. In an exemplary embodiment of the invention, portion 1412 is grasped by a tool, for example a tweezers, and pulled down, to the position shown in Fig. 14B. Spike 1408 may be pulled out of the graft by the motion. Possibly, the graft is first pulled off the spike. A plurality of positioning lines 1416 is shown. These lines may be used to indicate to the everter, how much of an oblique angle is generated by what amount of differential eversion. Alternatively or additionally, a line may be provided to mark a desired minimum eversion for portion 1410. Possibly, different line markings are provided for different vessel types and/or different anastomotic locations.

Figs. 15A-15C illustrate an alternative method of converting an even eversion into an oblique eversion, in accordance with an exemplary embodiment of the invention.

Fig. 15A is similar to Fig. 14A, except that a sliding pad 1516 is used instead of tweezers, to pull down a portion 1512 of a graft 1502 that is everted over a graft holder 1504 and spikes 1508.

Fig. 15B is a top view of fig. 15A, showing one or more inner barbs 1518 of pad 1516, engaging portion 1512, at or near spike 1508 or axially displaced therefrom. In Fig. 15C, pad 1516 is pulled down, carrying along portion 1512, causing the eversion to become oblique. As in Figs. 14, positional lines may be provided to indicate to an everted a desired degree of differential eversion.

Figs. 16A and 16B illustrate a cap-like tool 1616 for converting a perpendicular eversion into an oblique eversion, in accordance with an exemplary embodiment of the invention. In Fig. 16A, a graft 1602 is shown everted over a graft holder 1640, with two everted portions 1610 and 1614 having substantially equal lengths. It should be noted in this and other figures, that a cut-through figure is shown, focusing on only two points along the graft circumference (and only two spikes, if any). However, the techniques are generally applied to complete grafts (and connectors with multiple, e.g., 6-8 spikes).

In Fig. 16B a cap 1616 is provided, having an inner diameter slightly greater than the outer diameter of graft holder 1604. The cap includes a lip 1618, which may be longer adjacent portion 1612 than adjacent portion 1610. A barb 1620, or other means for engaging portion 1612 are provide inside lip 1618. In some cases, simply a roughening of the inner surface is sufficient to engage the graft. When cap 1616 is brought down, it pulls down portion 1612, and pulls down portion 1610 only slightly, if at all. An optional barb 1622 is provided for portion 1610 as well. This optional barb may be used to ensure that portion 1612 is not pulled too much relative to portion 1610 - by pulling down portion 1610 as well, when a desired relative eversion is reached. The barbs may be movable, for example, to allow a user to select different relative eversion amount. In an exemplary embodiment of the invention, the barbs comprises an oblique tube removably mounted inside cap 1616.

The degree of differential eversion depends of the application. For example, a normal eversion may be 1-3 mm, with a longer eversion being 1-7 mm. This can result in an eversion angle of between, for example 85° and 25°.

Figs. 3 and 8-16 show tools that may be used outside the body or inside the body, for example, transvascularly, endoscopicly or throactoscopicly. In an exemplary embodiment of the invention, the various caps are radially compressed and provided through the lumen of the graft. Alternatively, the caps may be provided as an over tube. In anther example, the various probes, tweezers and pads may be provided as an over tube. Wires or bars may be provided to providing retraction and rotation forces, respectively.

Once the graft is everted, it is typically provided into an incision in the target vessel. In an exemplary embodiment of the invention, the incision is formed using a hole punch. In an

exemplary embodiment of the invention, the hole punch also carries forward spikes of the anastomotic connector into the target vessel.

Fig. 17 illustrates an exemplary combined hole punch and connector inserter tool 1700, in accordance with an exemplary embodiment of the invention.

Tool 1700 comprises a body 1712 and a retractable tip 1714, that define a tissue receptacle 1716 between them. In operation, tip 1714 is inserted into a blood vessel (e.g., making a hole by virtue of its sharp tip or entering into an existing incision), so that the blood vessel tissue is captured by receptacle 1716. When tip 1714 is retracted, the tissue in the receptacle is punched out. Body 1712 is then advanced into the punched out hole. Optionally, the sharp tip portion of tip 1714 is retractable, to prevent damage to the opposite side of the target vessel, during the motion.

In an exemplary embodiment of the invention, an anastomotic connector is provided into the blood vessel by body 1712. In an exemplary embodiment of the invention, the connector is a two part connector, comprising a ring 1708 and a set of spikes 1710 inserted through the ring and an everted portion of a graft 1702. In an exemplary embodiment of the invention, spikes 1710 are mounted on a base 1706, which can be retracted, to perform the anastomosis.

In an exemplary embodiment of the invention, spikes 1710 include curved tips 1718 which are held in a recess 1720 in body 172. Thus, when body 1712 is advanced into the target vessel (possibly partially axially), the tips 1718 enter the vessel. Then the tips are retracted, they engage the vessel and pull the rest of the connector and everted graft 1702 to complete the anastomosis.

Various methods may be used to maintain tips 1718 inside recess 1720. In an exemplary embodiment of the invention, tips 1718 are pre-disposed (e.g. pre-bent or pre-stressed) to be bent inwards. Tips 1718 may be radially extended when spikes 1710 are retracted, by ring 1708 or by the widening of body 1712 outside of the recesses.

Optionally, tips 1718 may be mechanically held in recesses 1720. In an exemplary embodiment of the invention, recesses 1720 include a protrusion 1721 that is perpendicular to the figure plane. For example, the front view of recesses 1720 having the form of an "I". Thus, radial motion of tips 1718 is prevented. However, if body 1712 is rotated relative to tips 1720, the tips bypass the protrusion and can self-expand radially.

Figs. 18A and 18B illustrate a graft delivery system 1800, in accordance with an exemplary embodiment of the invention.

A graft 1802 is shown inserted through a hole 1814 in a graft holder 1804. For clarity, the everted tip of graft 1802 is not shown. however, it exits through an opening 1805 at the tip of graft holder 1804. Tips of a plurality of spikes 1808 are shown, such that graft holder maintains the spikes bent inwards, for example as shown in Fig. 10A and 10B, except that the tips of the spikes are allowed to protrude, for example as shown in Fig. 15A. A switch 1816 is provided to advance spikes 1808, thereby causing them to spring out and penetrate the graft (extension shown in Fig. 18B). A knob 1820 is provided for advancing the connector relative to graft holder 1804 and then retracting and removing the graft holder. Possibly, a safety 1818 is provided, to prevent inadvertent actuation of tool 1800.

In an exemplary embodiment of the invention, graft holder 1804 is removed by its retracting over a knife 1810, which splits the graft holder into two. The rest of graft holder 1804 is already split in two, for example at opening 1814. In an exemplary embodiment of the invention, the splitting line is not a shortest straight line, at least not between opening 1814 and knife 1810 (indicated by reference 1812), to prevent graft 1802 from catching on split line 1812.

In an exemplary embodiment of the invention, graft 1802 is inserted to opening 1805 by pushing it into opening 1814. Alternatively, graft 1802 is pulled, for example using a lasso (possibly similar to that described above) around its end, which is provided through opening 1804. During the motion of graft 1802 there is a danger that it will get caught on the spilt line. By providing a non-straight spilt line 1812, as shown, which does not meet opening 1814 at the along the device axis, but at its side, such catching is preferably prevented.

It will be appreciated that the above described methods and devices of vascular manipulation may be varied in many ways, including, changing the order of steps, which steps are performed inside the body and which outside, the order of making the anastomosis connections, the order of steps inside each anastomosis, the exact materials used for the anastomotic connectors, which vessel is a "side" side and which vessel (or graft) is an "end" side of an end-to-side anastomosis and/or whether two lips that are connected are from a same vessel or from different vessels. Further, in the mechanical embodiments, the location of various elements may be switched, without exceeding the sprit of the disclosure, for example, switching the moving elements for non-moving elements where relative motion is required. In addition, a multiplicity of various features, both of methods and of devices have been described. It should be appreciated that different features may be combined in different ways. In particular, not all the features shown above in a particular embodiment are necessary in every similar exemplary embodiment of the invention. Further, combinations of the above

features, from different described embodiments are also considered to be within the scope of some exemplary embodiments of the invention. In addition, some of the features of the invention described herein may be adapted for use with prior art devices, in accordance with other exemplary embodiments of the invention. The particular geometric forms used to illustrate the invention should not be considered limiting the invention in its broadest aspect to only those forms, for example, where a circular lumen is shown, in other embodiments an oval lumen may be used.

Also within the scope of the invention are surgical kits which include sets of medical devices suitable for making a single or a small number of anastomosis connections. Measurements are provided to serve only as exemplary measurements for particular cases, the exact measurements applied will vary depending on the application. When used in the following claims, the terms "comprises", "comprising", "includes", "including" or the like means "including but not limited to".

It will be appreciated by a person skilled in the art that the present invention is not limited by what has thus far been described. Rather, the scope of the present invention is limited only by the following claims.

## CLAIMS

1. A method of preparing a graft for an anastomosis, comprising:
providing a graft having a lip at an opening therein; and
compressing said lip of said graft to form at least one thickened portion adjacent said opening.

2. A method according to claim 1, wherein said thickening is uniform around said opening.

3. A method according to claim 1, wherein said thickening is non-uniform around said opening.

4. A method according to claim 3, wherein said thickening is non-uniform in length.

5. A method according to claim 3, wherein said thickening is non-uniform in thickness.

6. A method according to claim 3, wherein said thickening is selected to achieve a desired pre-stressing of said graft for an oblique anastomotic connection.

7. A method according to claim 1, wherein said thickening is selected to achieve a match between the lips of two vessels.

8. A method according to claim 1, wherein said thickening is selected to achieve a size match between the lip of the graft and the lip of an opening in a target vessel.

9. A method according to claim 1, wherein said thickening is selected to achieve a minimum size of seal area between the lip of the graft and the lip of an opening in a target vessel.

10. A method according to claim 1, comprising transfixing said thickening with at least one spike.

11. A method according to claim 1, wherein said spike is axially disposed with respect to said graft.

12. A method according to claim 1, wherein said spike is obliquely disposed with respect to said graft.

13. A method according to claim 1, wherein said thickening is maintained in shape by a connector.

14. A method according to claim 1, wherein compressing said lip comprises compressing using an anastomotic connector.

15. A method according to claim 1, wherein compressing said lip comprises compressing using a graft compression tool.

16. A method according to claim 1, wherein compressing said lip comprises everting an intima of said graft at least 90°.

17. A method according to claim 1, wherein compressing said lip comprises everting an intima of said graft at least 120°.

18. A method according to claim 1, wherein compressing said lip comprises everting an intima of said graft at least 160°.

19. A method according to claim 16, wherein said everting matches said intima to an intima of a target vessel.

20. A method according to claim 1, wherein said opening is an opening in side of said graft.

21. A method according to claim 1, wherein said opening is an opening in an end of said graft.

22. A method according to any of claims 1-21, wherein said graft is a blood vessel.

23. A method according to claim 22, wherein said graft is a mammary artery.

24. A method according to any of claims 1-21, wherein said graft is a synthetic graft.

25. A method according to any of claims 1-21, comprising attaching said graft to a blood vessel.

26. A method according to any of claims 1-21, comprising attaching said graft to a synthetic graft.

27. A connector adapter to be distorted for oblique connections, comprising:

a plurality of interconnected segments, at least some of said segments including a forward spike or a backward spike; and

a plurality of distortable portions defined between said segments, wherein said portions are adapted to support a distortion from a straight anastomosis to an oblique anastomosis.

28. A connector according to claim 27, wherein said distortable portions comprise at least one ring.

29. A connector according to claim 27, wherein said distortable portions are designated in a ring that interconnects said segments.

30. A connector according to claim 27, wherein said distortable portions are annealed.

31. A connector according to claim 27, wherein said spikes are self extending.

32. A connector according to claim 27, wherein said distortable portions are plastically deformable.

33. A connector according to claim 27, wherein said distortable portions are pre-stressed to mach an oblique connection configuration.

34. A connector according to claim 27, wherein said distortable portions are unevenly distributed on said connector.

35. A connector according to claim 34, wherein said distribution matches an expected amount of distortion at the different parts of said connector.

36. A method of creating an oblique eversion in a graft, comprising:
everting a graft to have a straight everted sleeve; and
differentially extending one side of the sleeve, to form an oblique eversion.

37. A method according to claim 36, wherein said everting comprises everting over a connector having spikes.

38. A method according to claim 37, wherein said spikes are fully extended during said everting.

39. A method according to claim 38, comprising assisting said spikes to penetrate said sleeve after said differentially extending.

40. A method according to claim 37, wherein said spikes are partially extended during said everting.

41. A method according to claim 40, comprising fully extending said spikes to penetrate said sleeve.

42. A method according to claim 37, wherein said spikes are not extended during said everting.

43. A method according to claim 37, wherein differentially extending comprises extending only part of said sleeve.

44. A method according to claim 37, wherein differentially extending comprises extending all of said sleeve.

45. A method according to claim 37, wherein differentially extending comprises manually pulling down said side using tweezers.

46. A method according to claim 37, wherein differentially extending comprises pulling down said side using a pad that slides along said graft, which pad includes a vessel engaging element to engage said side.

47. A method according to claim 37, wherein differentially extending comprises pulling down said side using a tube that slides along said graft, which tube includes a vessel engaging element to engage said side.

48. A method according to claim 47, wherein said tube comprises at least a second vessel engaging element, to engage an opposite side of said sleeve.

49. A method according to claim 47, wherein said tube is capped, to prevent over sliding of said tube over said graft.

50. A method of creating an oblique eversion in a graft, comprising:

mounting said graft inside a graft holder having a slotted axial extension;

mounting a connector on said graft such that a spike of said connector exits through said slot; and

everting said graft on said tube, such that a portion everted over said extension is longer than a portion everted not over said extension.

51. A method of penetrating non-perpendicular pointing spikes of a connector into an everted graft, comprising:

radially compressing said spikes;

everting said graft over said connector; and

suddenly releasing said spikes, to penetrate said graft.

52. A method according to claim 51, wherein said radially compressing aligns said spikes to be more perpendicular to said graft.

53. A method according to claim 51, wherein radially compressing comprises restraining said spikes using a slotted tube and wherein suddenly releasing comprises rotating said tube so that said spikes align with and pass through said slots.

54. A method according to claim 53, wherein all of said spikes are aligned simultaneously with said slots by said rotation.

55. A method according to claim 53, wherein not all of said spikes are aligned simultaneously with said slots by said rotation.

56. A method according to claim 51, wherein radially compressing comprises restraining said spikes using an over-tube and wherein suddenly releasing comprises retracting said tube relative to said spikes so that said spikes are released.

57. A method according to claim 56, wherein said over-tube comprises a graft holder for said graft.

58. A method according to claim 56, wherein said over-tube is separate from a graft holder for said graft.

59. A method according to claim 56, wherein retracting said tube relative to said spikes comprises advancing said connector.

60. A method according to claim 56, wherein retracting said tube relative to said spikes comprises retracting said over-tube.

61. A method according to claim 51, wherein said spikes are partially extended so they can contact said graft, prior to said suddenly releasing.

62. A method according to claim 51, wherein said spikes are not all the same length, so that when released they do not all penetrate said graft at a same time.

63. A method according to claim 53 or claim 56, wherein said tube is oblique.

64. A method according to claim 51, wherein radially compressing comprises restraining said spikes using a looped thread.

65. A method according to claim 64, wherein said looped thread comprises a slipknot.

66. A method of penetrating non-perpendicular pointing spikes of a connector into an everted graft, comprising:

everting said graft over said connector;

placing a cap on said everted graft; and

manipulating said cap to cause penetration of said spikes into said graft.

67. A method according to claim 66, wherein manipulating comprises rotating said cap.

68. A method according to claim 66, wherein manipulating comprises axially displacing said cap.

69. A method of everting a graft, comprising:

mounting said graft in a graft holding tube;

providing a conical membrane inside a lumen of said graft; and

everting said membrane to effect an eversion of said graft.

70. A method according to claim 69, wherein said conical membrane comprises a relatively rigid base ring.

71. A method according to claim 69, wherein said conical membrane comprises a relatively rigid extension from its tip.

72. A method according to claim 69, wherein said everting comprises obliquely everting said conical membrane.

73. A split graft holder, comprising:

a tube having a tip for the exit of a graft, defining:

a side opening for receiving the graft through a lumen of said tube to said tip; and

a split line along said tube axis and meeting said side opening, for splitting said holder to remove said holder from a graft, after said graft is attached to another blood conduit, wherein

said split line does not axially meet said side opening, at a side of said opening near said tip of said tube.

74. A graft holder according to claim 73, wherein said split line meets said opening from its side.

75. A reducing profile anastomotic connector, comprising:

a ring section;

a spikes section comprises a plurality of spikes, wherein said spikes section defines a collapsing portion, for axial collapsing of said spikes section.

76. A connector according to claim 75, wherein said collapsing portion buckles.

77. A connector according to claim 75, wherein said collapsing portion twists.

78. A connector according to claim 75, wherein said collapsing portion folds out.

79. A connector according to any of claims 75-78, wherein said collapsing portion self-deforms.

80. A connector according to any of claims 75-78, wherein said collapsing portion plastically deforms.

81. A combined hole punching and graft delivery device, comprising:

a body, having therein at least one recess for receiving a spike of a connector; and

a sharp tip retractable relative to said body, wherein said sharp tip and said body define between them a blood vessel wall receiving area.

82. A device according to claim 81, wherein said recess includes a protrusion, for selectively releasing said spike when said body is rotated relative to said spike.

83. A device according to claim 81, wherein said spike is pre-stressed to self extend out of said recess.

84. A device according to claim 81, wherein said spike radially extends out of said recess when it is retracted.

85. A graft everting tool, comprising:

a base ring;

an extension adapted to be inserted in a graft; and

a conical membrane-like element connecting said base and said extension, and adapted to engage an inside of a blood vessel,

wherein said membrane is flexible enough to be everted.

86. A tool according to claim 85, wherein said tool is adapted to evert obliquely.

87. A tool according to claim 85, wherein said tool has a non-uniform graft property, so as to effect an oblique eversion when it is used to evert a graft.

88. A tool for compressing a tip of a graft, comprising:

an outer mandrel mounted over the graft and reaching to about an opening in the graft;

an inner mandrel mounted inside the graft and reaching to about said opening; and

a base,

wherein said base and said two mandrel define a space for said graft to extend into when the mandrels are brought together.

89. A tool according to claim 88, wherein said inner mandrel is mounted on said base.

90. A tool according to claim 88, wherein said inner mandrel is expandable.

91. A tool according to claim 88, wherein said inner mandrel is adapted to engage at least a portion of said graft.

92. A tool according to claim 88, wherein said outer mandrel is adapted to engage at least a portion of said graft.

93. A tool for forming an oblique eversion from a graft everted over a graft holder, comprising:

a body shaped to slide over said everted graft; and

at least one graft engaging element for selectively engaging only one side of said everted graft.

94. A tool according to claim 93, wherein said body comprises a tube.

95. A tool according to claim 93, wherein said body comprises a tube segment.

96. A tool according to claim 93, wherein said body is capped to prevent axial motion beyond a certain amount.

97. A tool according to claim 93, comprising at least a second graft engaging element for engaging a second side of said everted graft.

98. A tool for forming an oblique eversion for a graft, comprising:

a tube; and

at least one axial extension of said tube, such that a spiked connector disposed in said tube can project at least one of its spikes near a base of said projection.

99. A tool according to claim 98, wherein said at least one projection comprises at least two projections defining a slot between them, with said spike extending through said slot.

100. A tool for forming an oblique eversion for a graft, comprising:

a tube adapted for having a graft and a connector mounted therein; and

an over-tube which radially restrains at least one spike of said connector, wherein said connector can be moved relative to said over-tube.

101. A tool according to claim 100, wherein said over tube is slotted and wherein said motion is rotation.

102. A tool according to claim 100, wherein said motion comprises axial motion of said connector relative to said over-tube.

103. A tool according to claim 102, wherein said tube is a same element as said over tube.

104. A tool according to claim 100, wherein said over-tube is oblique.

105. A tool for assisting spike penetration into an everted graft; comprising:
a graft and connector holder having a graft everted thereon; and
a cap having an inner diameter larger than an outer diameter of said graft and connector holder, for mounting on said everting graft.

106. A tool for assisting spike penetration into an everted graft; comprising:
a handle, defining at least two arms; and
a wire between said two arms,
wherein said tool is adapted for assisting penetration of a spike into an everted graft.

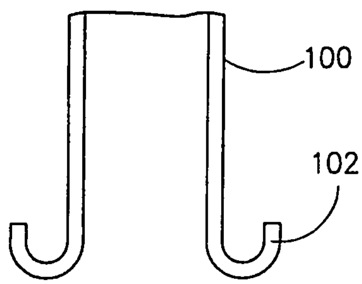


FIG.1A
PRIOR ART

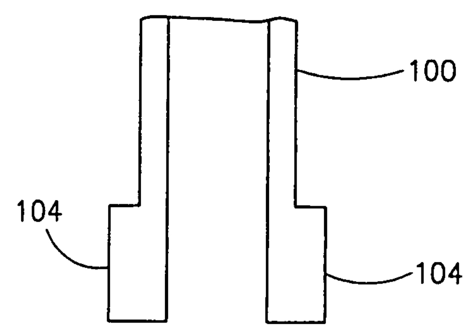


FIG.1B

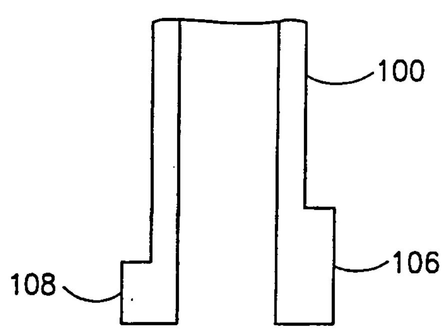


FIG.1C

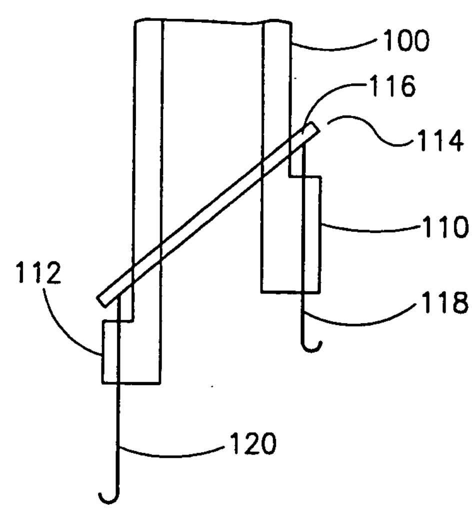


FIG.1D

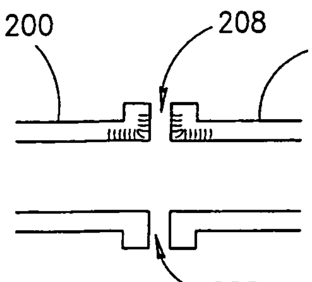


FIG.2A

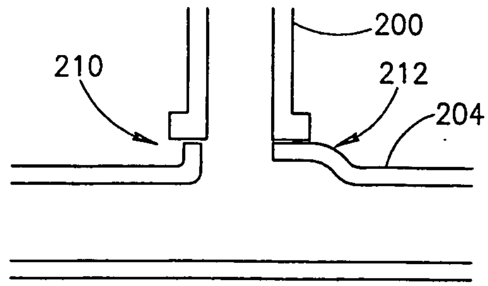


FIG.2B

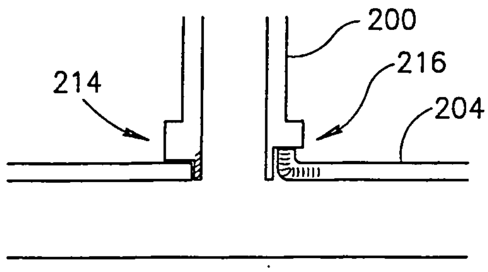


FIG.2C

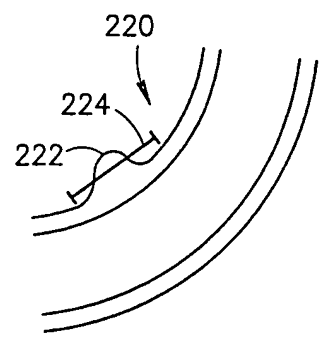


FIG.2D

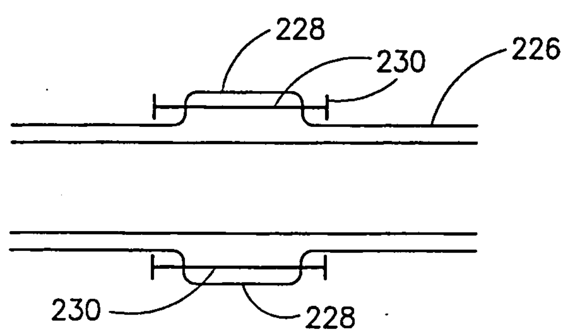


FIG.2E

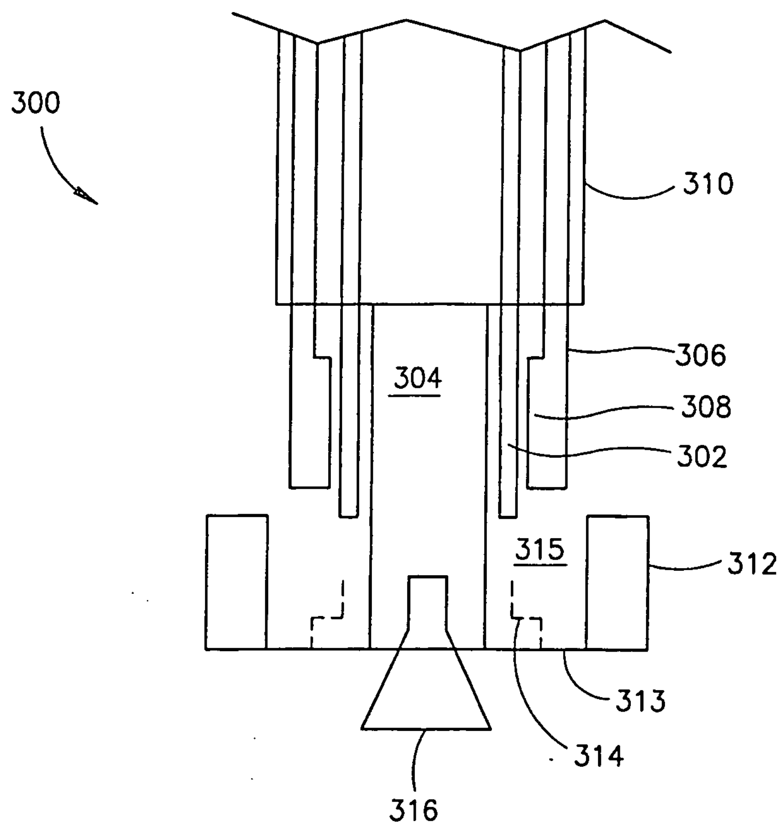


FIG.3

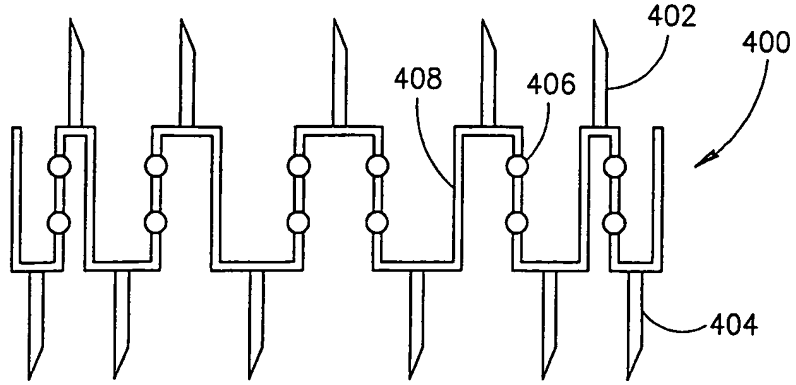


FIG.4A

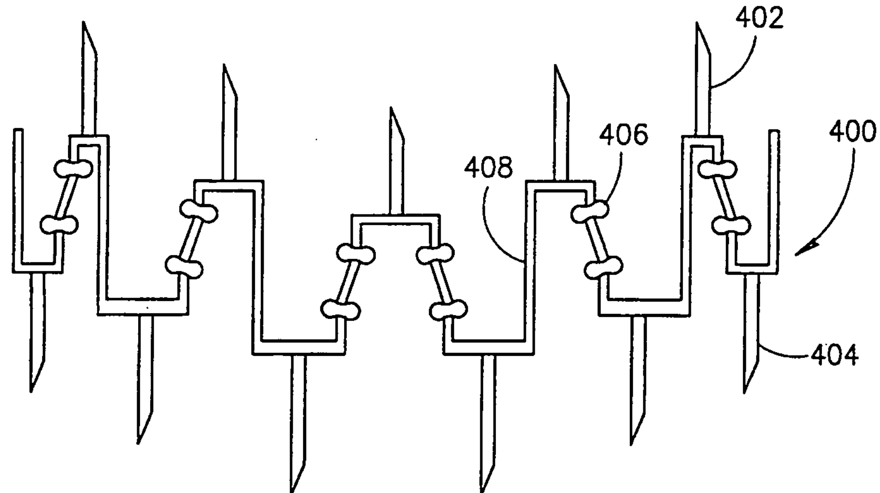


FIG.4B

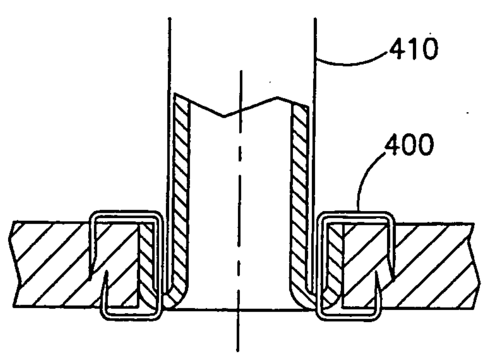


FIG.4C

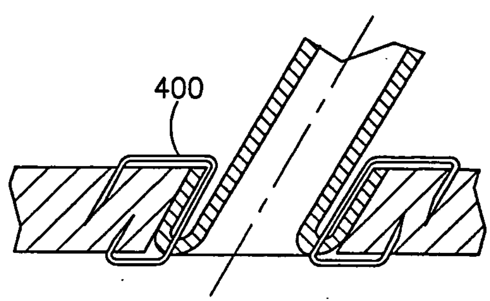


FIG.4D

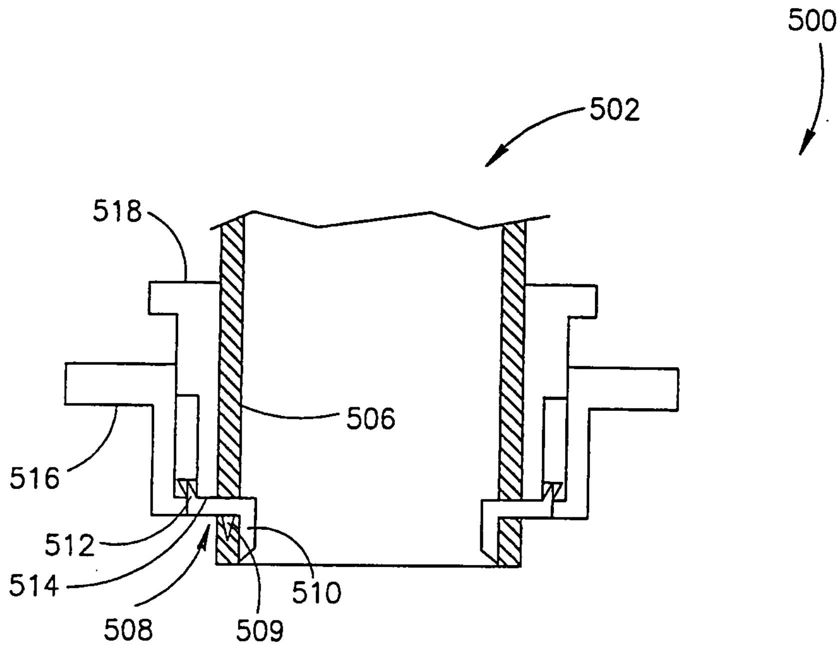


FIG.5A-1

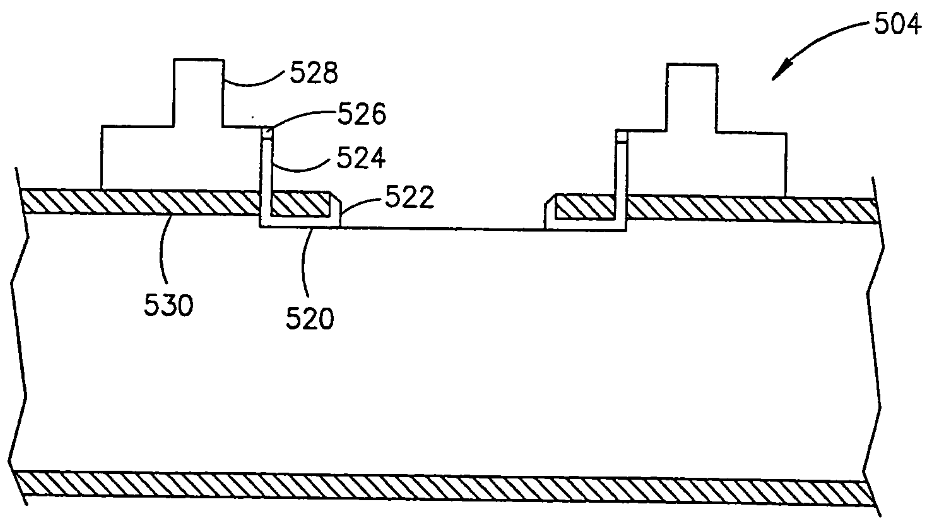


FIG.5A-2

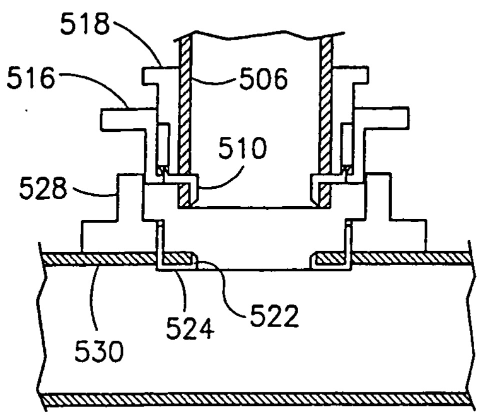


FIG.5B

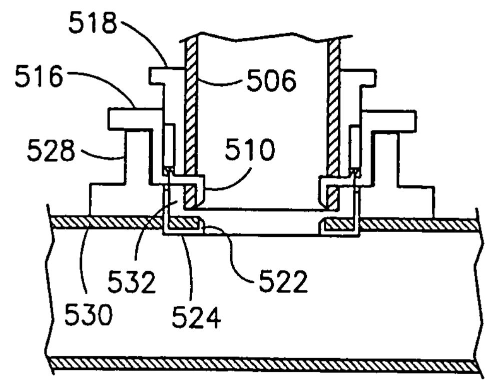


FIG.5C

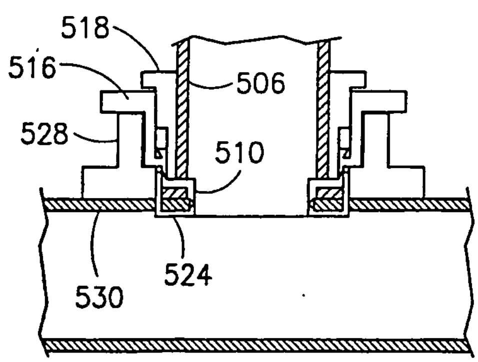


FIG.5D

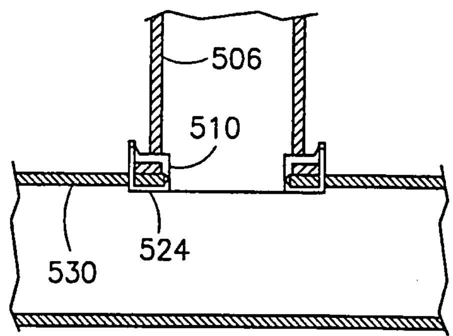


FIG.5E

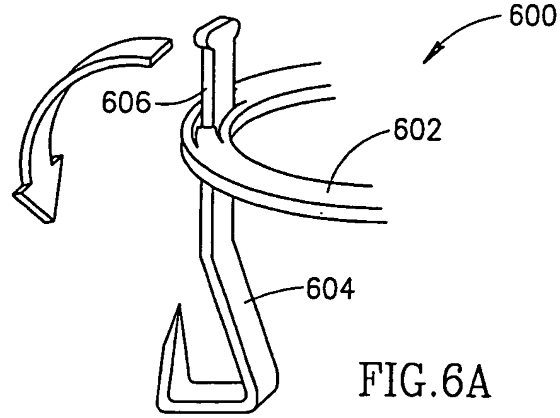


FIG.6A

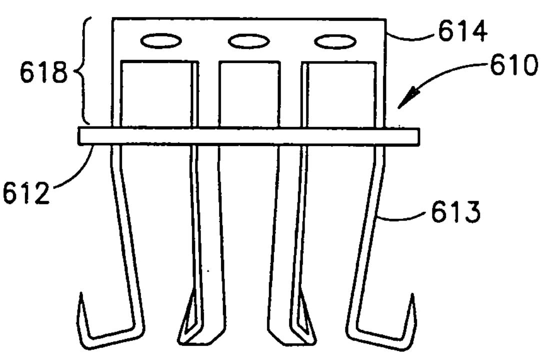


FIG.6B

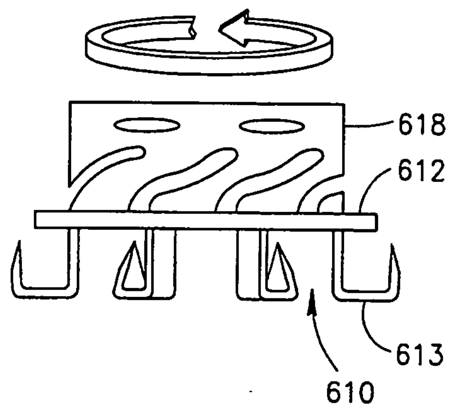


FIG.6C

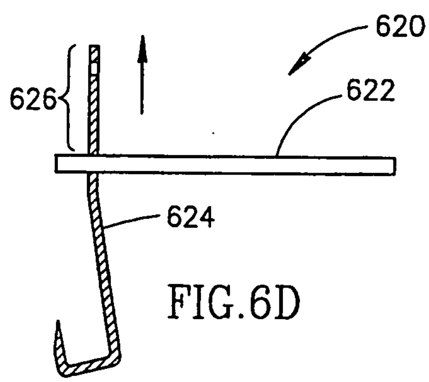


FIG.6D

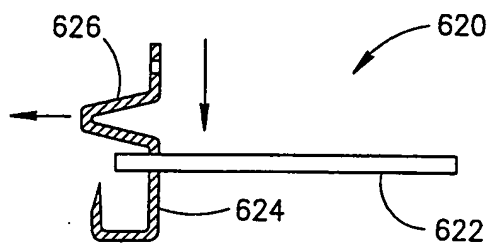


FIG.6E

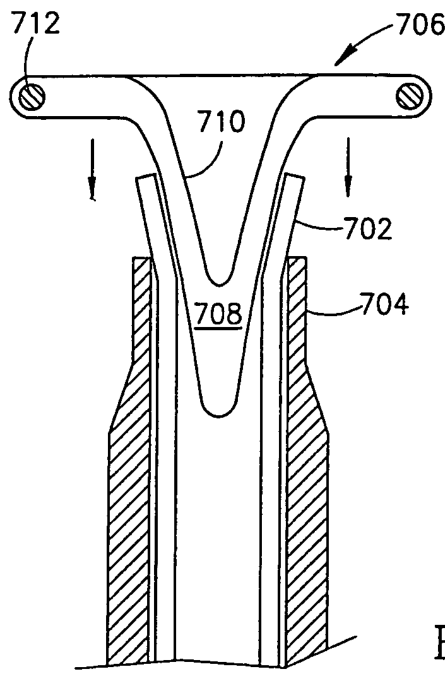


FIG.7A

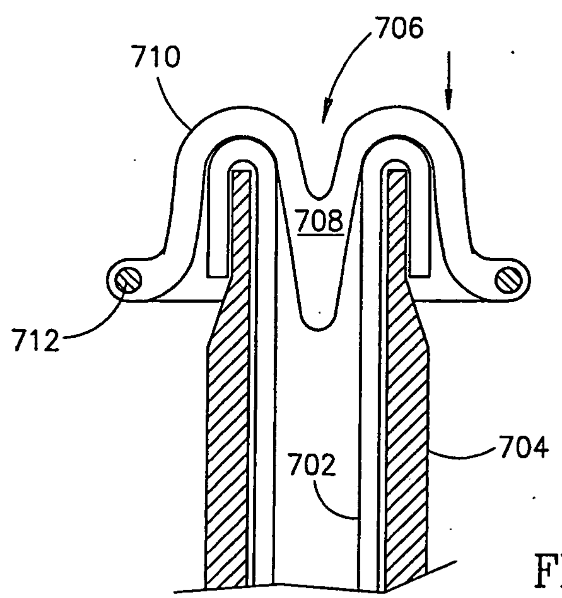


FIG.7B

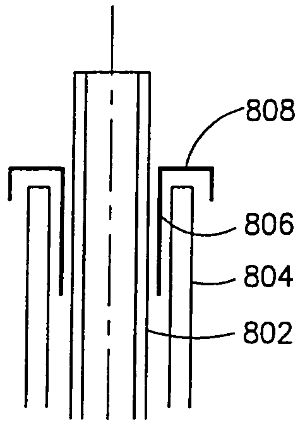

FIG.8A

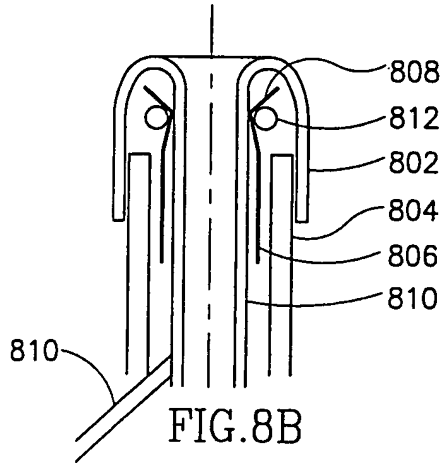

FIG.8B

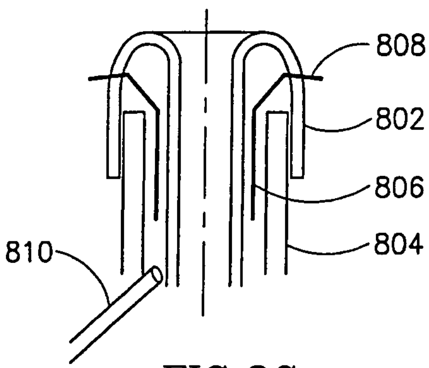

FIG.8C

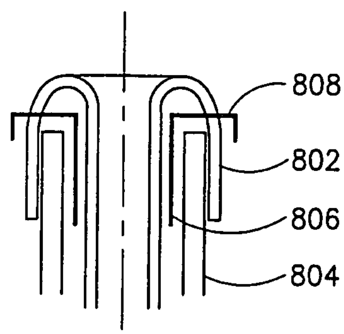

FIG.8D

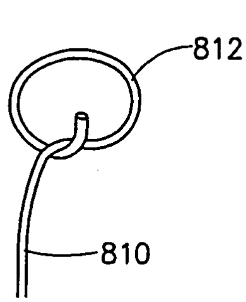

FIG.8E

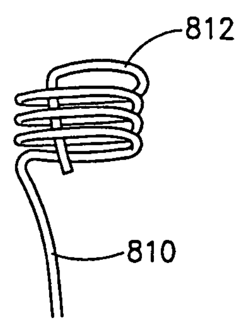

FIG.8F

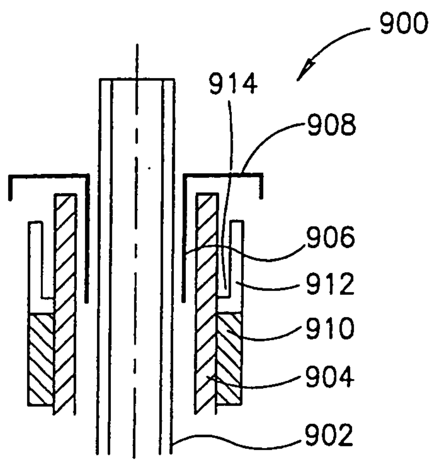


FIG.9A

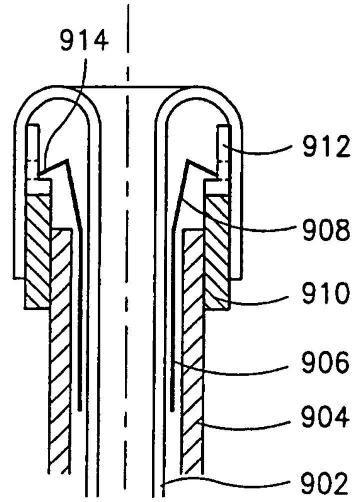


FIG.9B

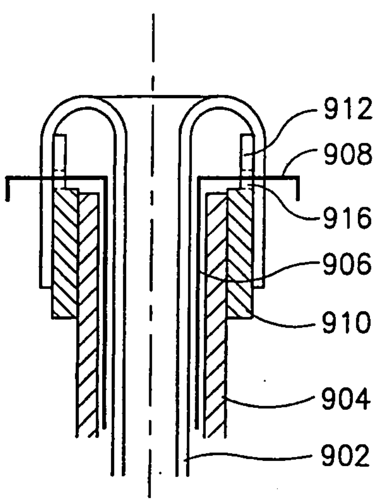


FIG.9C

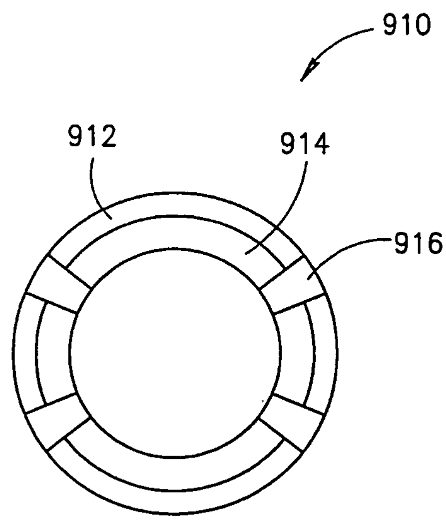


FIG.9D

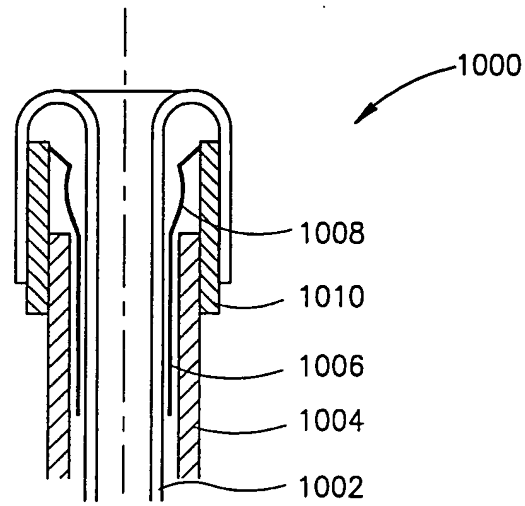


FIG.10A

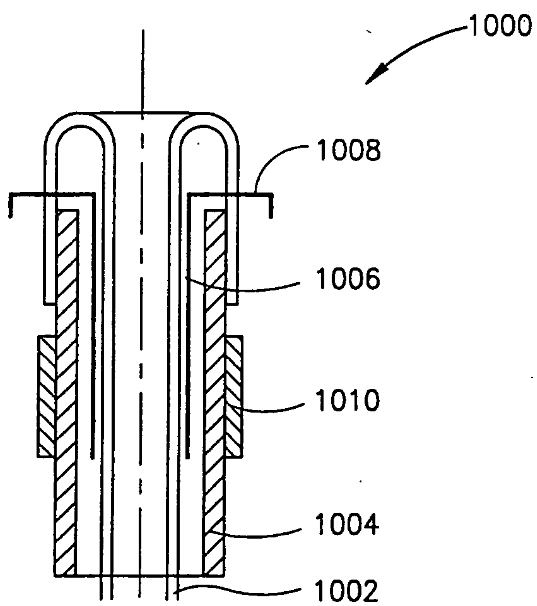


FIG.10B

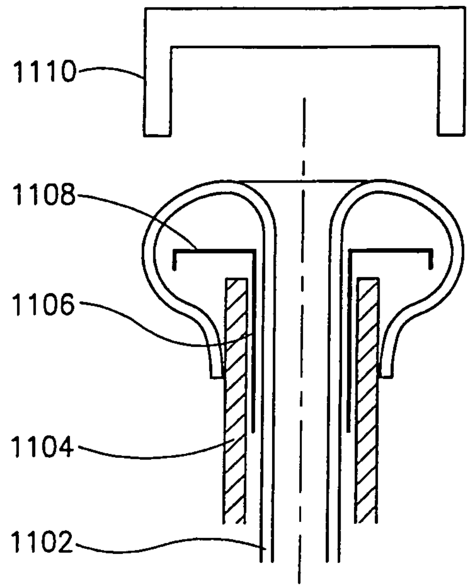


FIG.11A

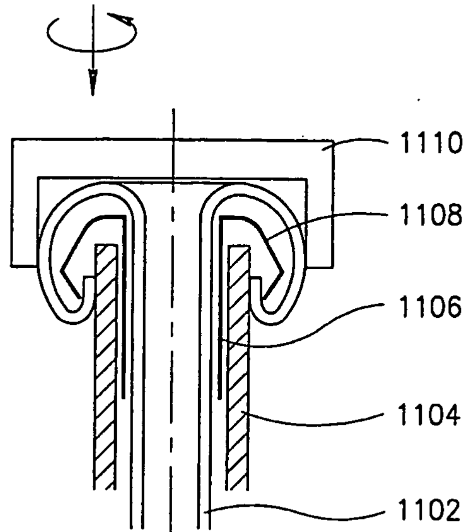


FIG.11B

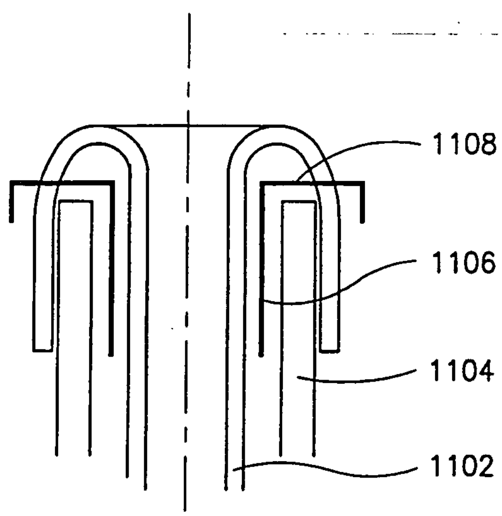


FIG.11C

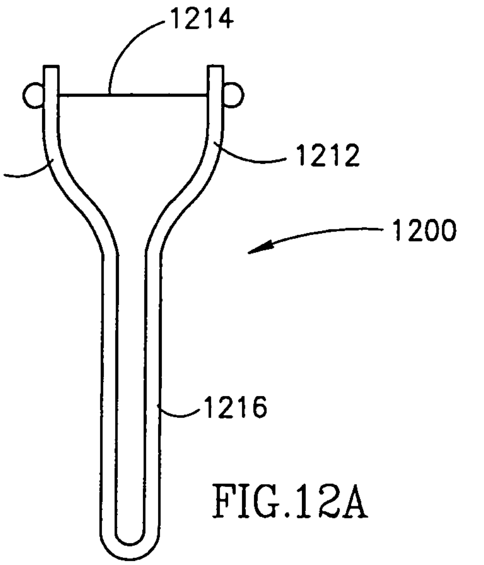


FIG.12A

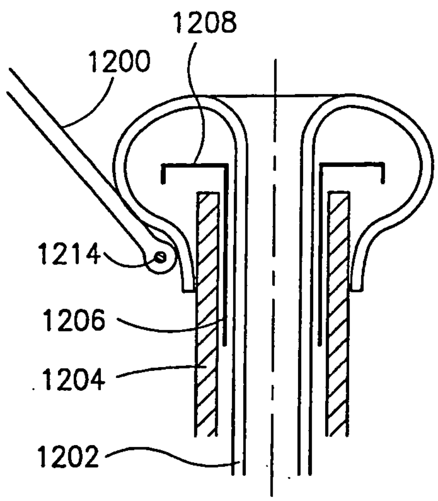


FIG.12B

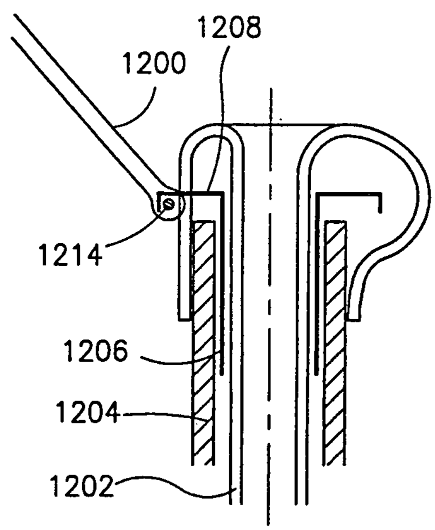


FIG.12C

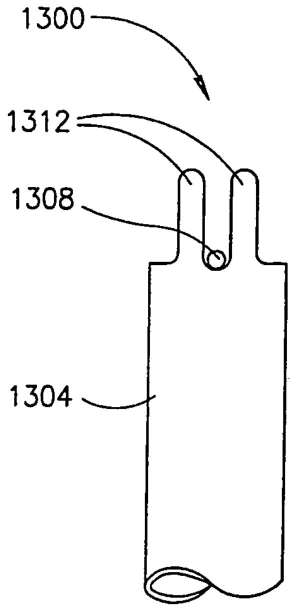


FIG.13A

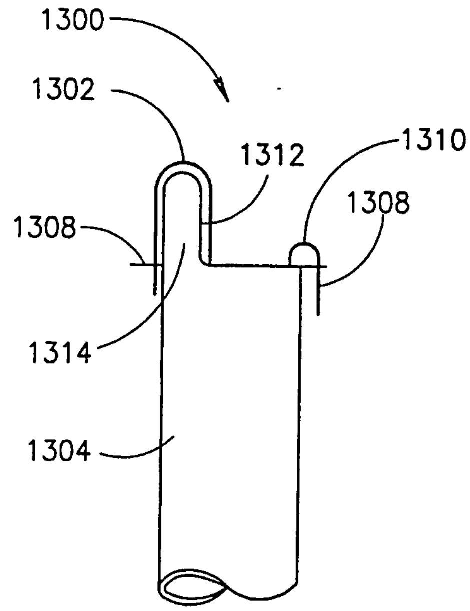


FIG.13B

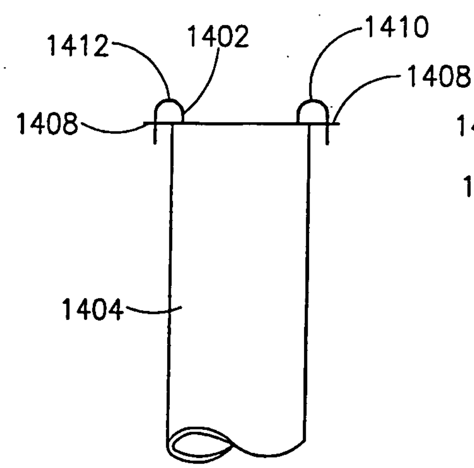


FIG.14A

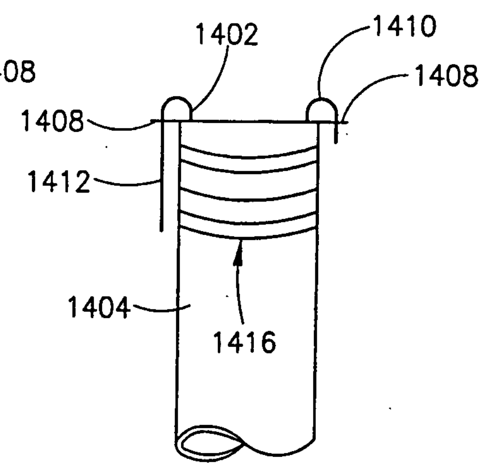


FIG.14B

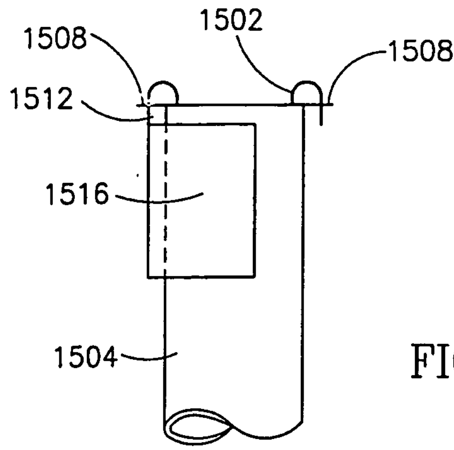


FIG.15A

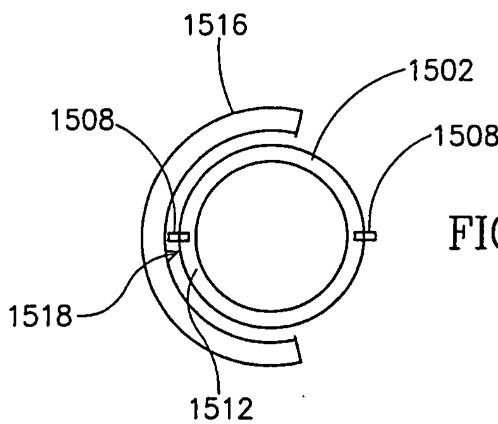


FIG.15B

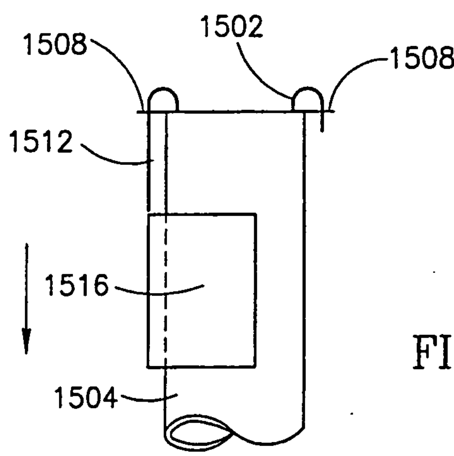


FIG.15C

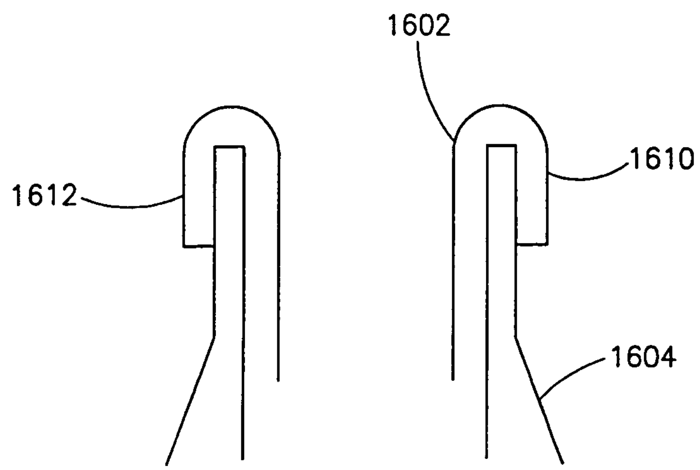


FIG.16A

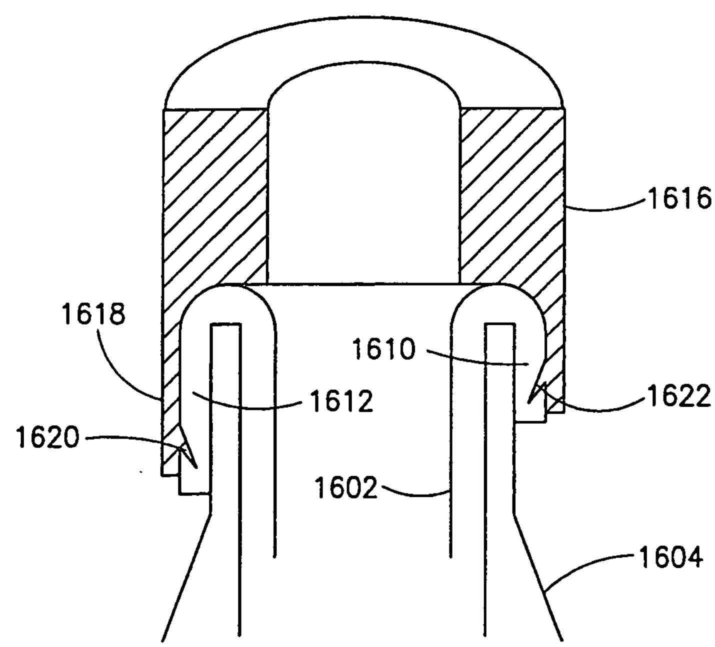


FIG.16B

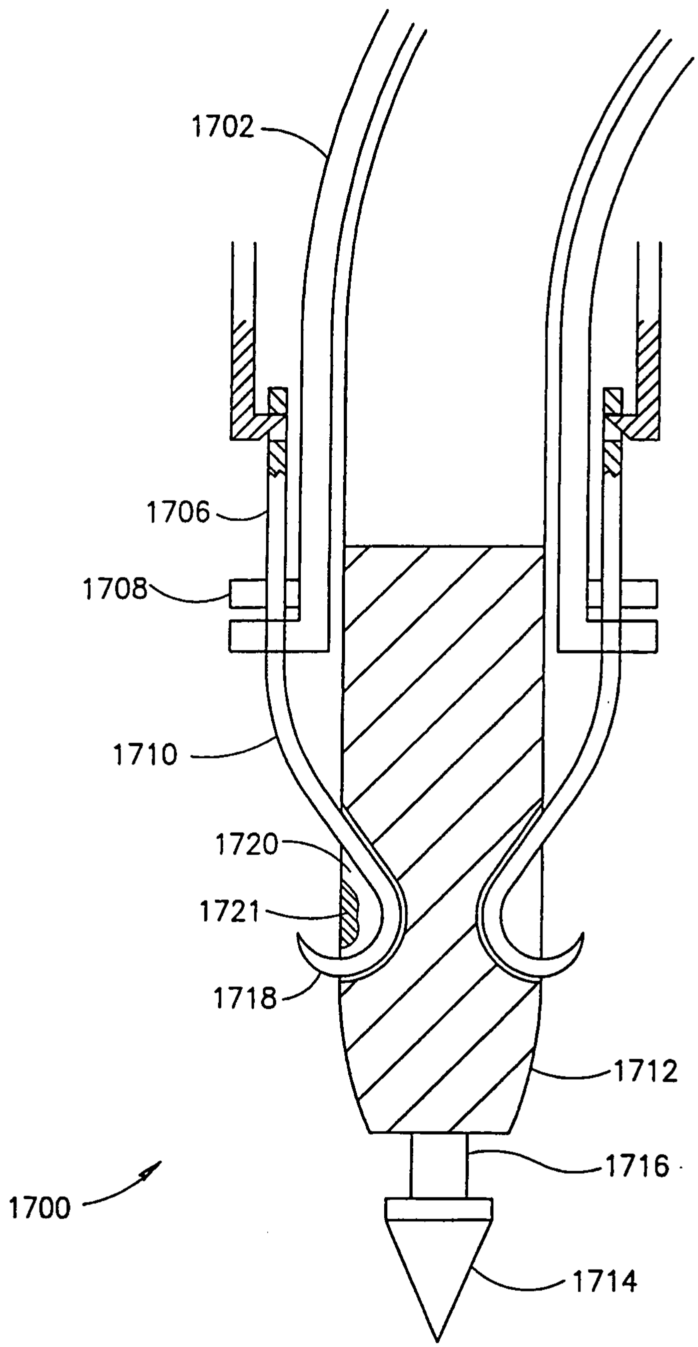


FIG.17

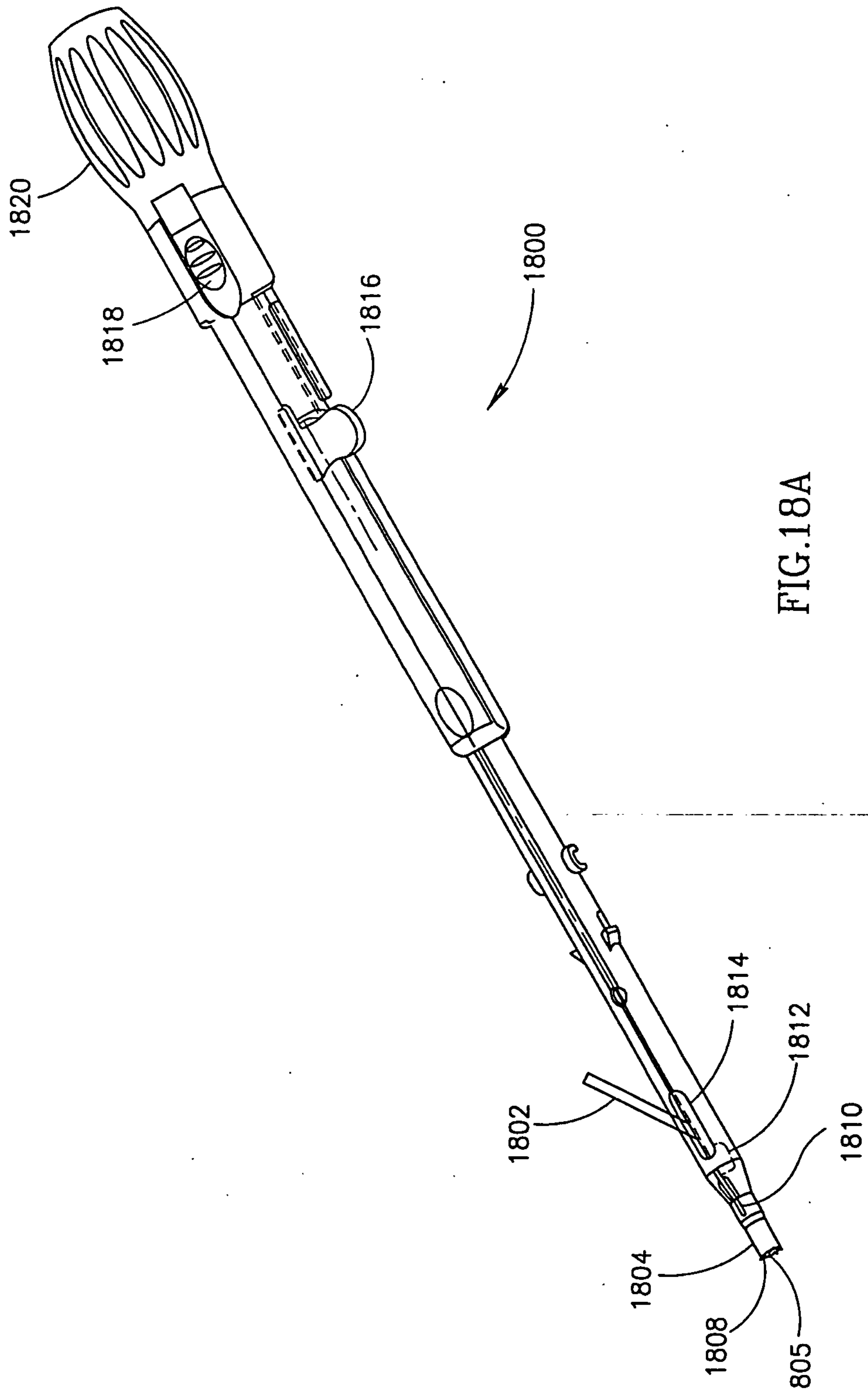


FIG.18A

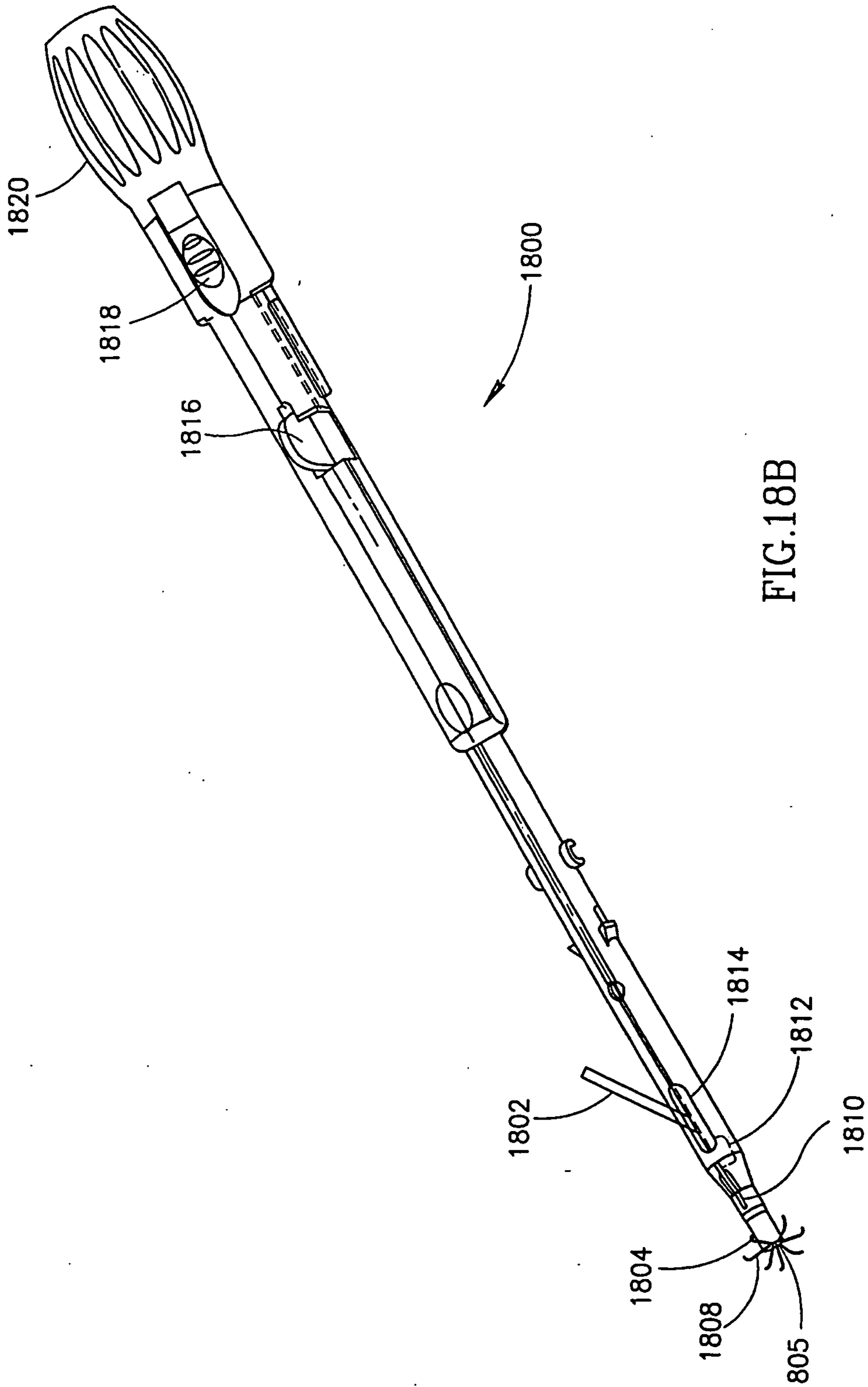


FIG.18B